BodyGuard 323

Infusion Pump System
Operator Manual

CE 0344

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☞ NOTE: *To assure proper use of the BodyGuard, Caesarea Medical Electronics Ltd. urges all users to read this manual carefully, become familiar with the procedures and system functions and follow all recommendations.*

⚠ ***Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary. Please contact your technician in order to enable the air sensor if disabled with no need.***

⚠ U.S.A. federal law restricts this device to sale by or on the order of a physician.

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1- Introduction

Overview

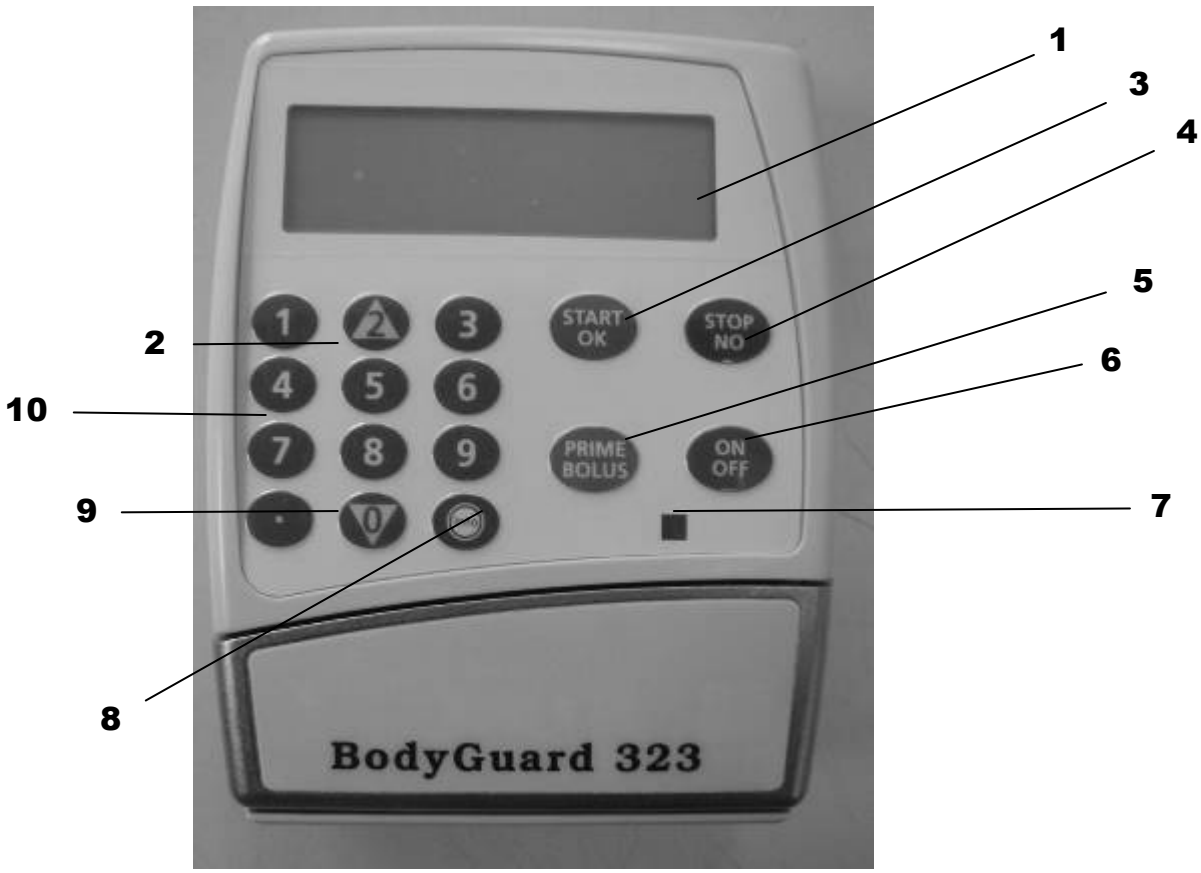
The *BodyGuard* System provides the following features:

- Small, light and compact pump.
- Multiple Programs:

Continuous	Infusion Rate: 0.1 to 1200 ml/hr Volume: 0.1 to 99.9 ml in 0.1ml increments or 1 to 9999 ml in 1ml increments Secondary Infusion (Piggy) programmable with the same infusion rate and volume capabilities as the primary continuous infusion.
Intermittent	A set dose delivered in set intervals. Between Intervals the pump will keep vain open (KVO Mode).
TPN	Total Parenteral Nutrition Rate Taper program with programmable up and down times.
PCA	Patient Control Analgesia: Continuous delivery plus /or programmed boluses. Bolus Volume: 0-25.5 ml Clinician Bolus Volume: 0.1-100ml Bolus Rate: 0.1-1200 ml/h
25 Steps	Operator can design a specific protocol for drug delivery which contains up to 25 steps. Infusion Rate: 0.1 to 1200 ml/hr Volume: up to 9999ml, for each step Accumulated Volume for all steps – up to 10 liters.

- Highly accurate fluid delivery
- Operated with a custom safe administration set
- Rechargeable internal lithium-ion battery or alkaline 2X9V batteries
- Battery charged in a pole mount charging cradle or with an A/C adaptor
- Free flow protection valve standard on every CME administration set
- Quiet operation
- Used for ambulatory care in a carrying pouch or mounted on an IV pole
- AEA – Suitable to be used in ambulances.

Front of *BodyGuard* Infusion Pump



1. Display Screen

- Displays pump and infusion status
- Displays programming choices and instructions

2. Up Arrow

- Scrolls up through options

3. START/ OK

- Starts infusion
- Confirms selection and setting

4. STOP/NO

- Stops infusion
- Silences an alarm condition
- Pause priming
- Zeroes the displayed value during programming
- Erases the last digit during programming
- Returns to previous screen

5. PRIME/BOLUS

- Pressing Prime/Bolus key *during data setting*: Enables Priming procedure. A graph appears on the display screen showing the priming volume with the current value increasing until reaching the set volume.
- Pressing Prime/Bolus key during *Continuous* program operation: Enables Secondary (Piggy) Infusion.
- Pressing Prime/Bolus key during *PCA* program operation: Enables bolus procedure.

6. Power ON/OFF

- Turn the system ON by pressing and holding the button until the Self-Test screen appears.
- Turn the system OFF by pressing and holding the button until the graph is black and a beep is generated.

7. Operation LED

- *Green Indicator*
  - Lights during system Self-Test
  - An intermittent green light indicates infusion delivery
- *Red Indicator*
  - Indicates an alarm state with a continuous red light
  - Lights when the pump is in a stand-by mode during programming

8. INFO

- Supplies information about the pump and its programs (see Info Mode chapter).
- Pressing continuously locks and unlocks the keypad to prevent accidental or deliberate change to pump operation (If needed).

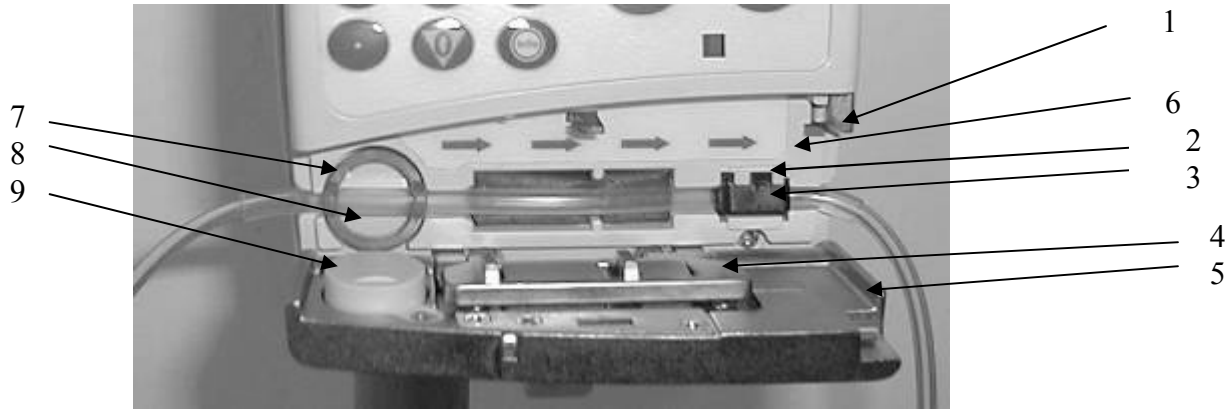
9. Down Arrow

- Scrolls down through options

10. Numeric Keys

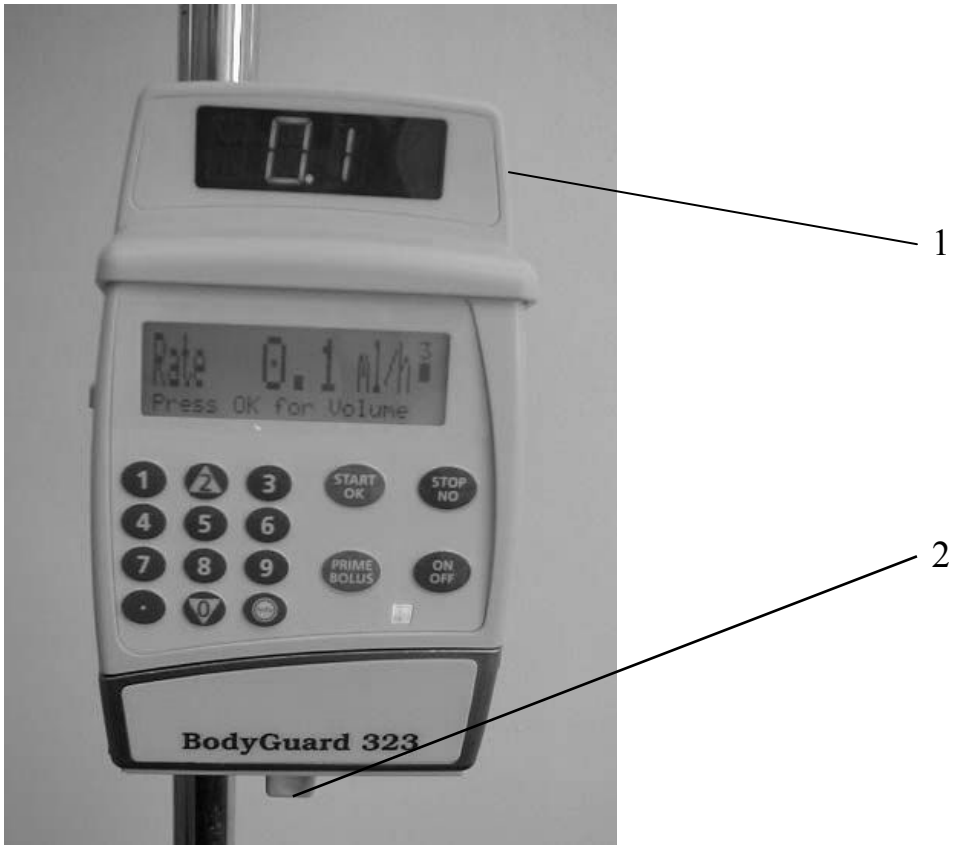
- Enters numeric parameters during programming

BodyGuard Pump with Door Open



#	Area	Function
1.	Latch Holder	Holds the door closed when latch is in vertical position.
2.	Pressure Sensor	Detects downstream tubing restriction and occlusion. Alarm level can be adjusted to suit patient needs.
3.	Keyway	Guides the IV line
4.	Pressing Plate	Connected to the door by two springs
5.	Pump Door	Covers the pressing plate
6.	Flow Direction	Shows direction of pump operation
7.	Anti-Stretch locator (Optional)	Locates the tube in the correct length from the key
8.	Air sensor – Front	Ultrasonic air detector, which is mounted on the front housing.
9.	Air sensor - Door	Mounted on the door

The Charger



#	Area	Function
1.	Charger Display	Displays major pump messages and operation values.
2.	Release Handle	Push to release the pump from the Charger.

System Safety Checks

The following details outline the safety checks designed into the *BodyGuard* infusion system, to minimize the possibility of under or over infusions.

Free Flow Protection

The system's customized IV lines are equipped with a check valve that prevents free flow towards the patient when the IV line is not attached to the pump. When the pump is attached to the IV line and delivering fluid, the pressure delivered by the pump opens the valve. The valve is also one way valve preventing fluids flow from the patient to the administration line.

Air-in-Line Accumulation

To improve the detection of air in the IV line, the *BodyGuard 323* Infusion system utilizes an air-in-line accumulation system in addition to the standard single bubble detection. This feature monitors the volume of air that passes through the IV line by accumulating the volume of individual bubbles over any 15 minutes period. This limit is not configurable. Although an individual bubble may not exceed the pre-programmed threshold, if the cumulative volume of smaller bubbles exceeds 1ml over a period of 15 minutes an air-in-line alarm is initiated. This accumulation feature is particularly useful with infusions for patients who are highly sensitive to air (i.e. infants, neonates, children) or when infusing products that create significant volumes of small air bubbles.

Anti-Bolus Function

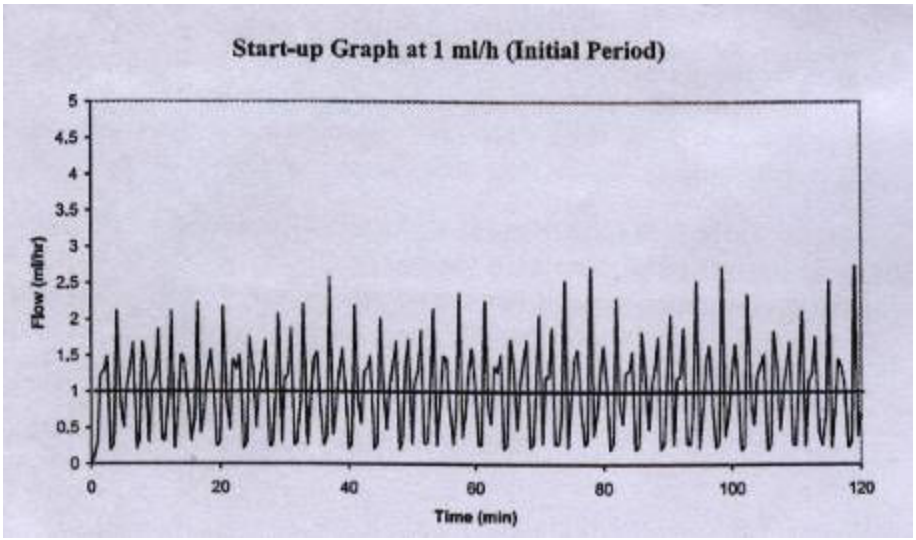
The anti-bolus function is designed to reduce the bolus that may occur upon the release of an occlusion following a downstream occlusion alarm. Upon the detection of a downstream occlusion, the alarm is activated and the pump returns the IV line pressure to neutral within 15 seconds. Neutral line pressure is achieved by the reverse operation of the pumping mechanism, and measurement of the IV line pressure through the in-line pressure detection system.

Pump Accuracy

The following graphs and curves were derived from testing described in IEC60601-2-24. Testing was performed under normal conditions at room temperature (72^0 F). Any deviations from normal conditions and room temperature may cause changes in the accuracy of the pump.

Start-up Curves

The Start-up curves represent continuous flow versus operating time for two hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data. Tests performed according to IEC 60601-2-24 standard.



Trumpet and Flow Rate

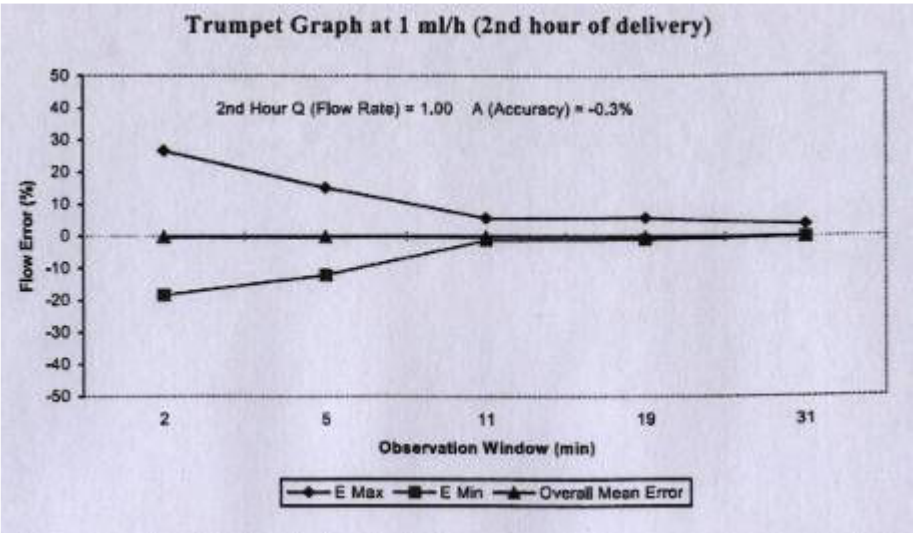
With the *BodyGuard 323*, as with all infusion systems, the action of the pumping mechanism and variations cause short term fluctuations in rate accuracy.

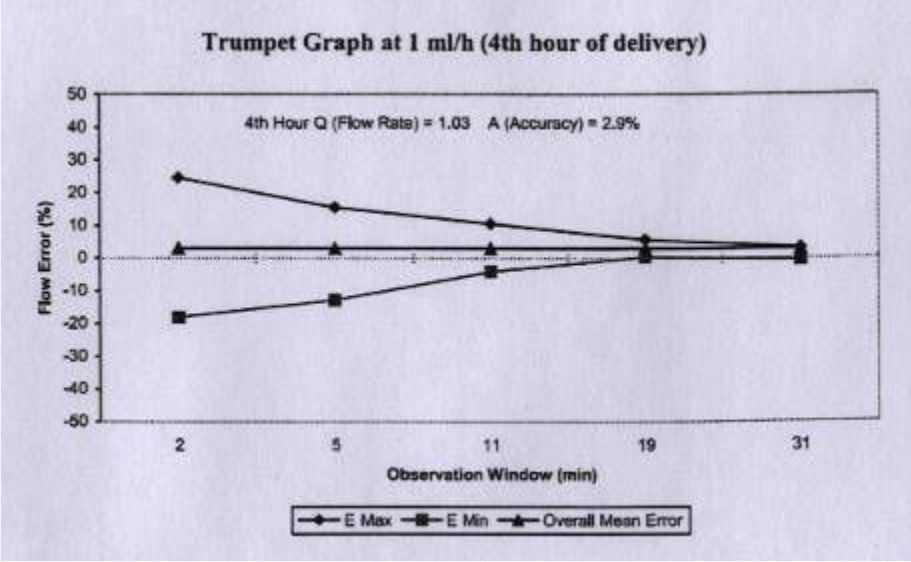
The following curves show typical performance of the system in two ways:

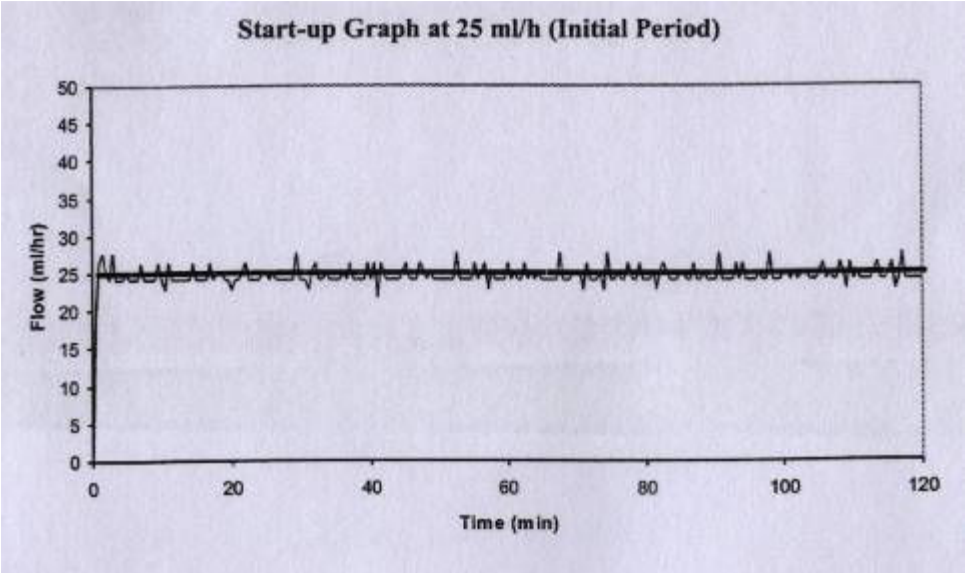
1. The accuracy of fluid delivery over various time periods is measured (trumpet curves).
2. The delay in onset of fluid flow when infusion commences (start up curves).

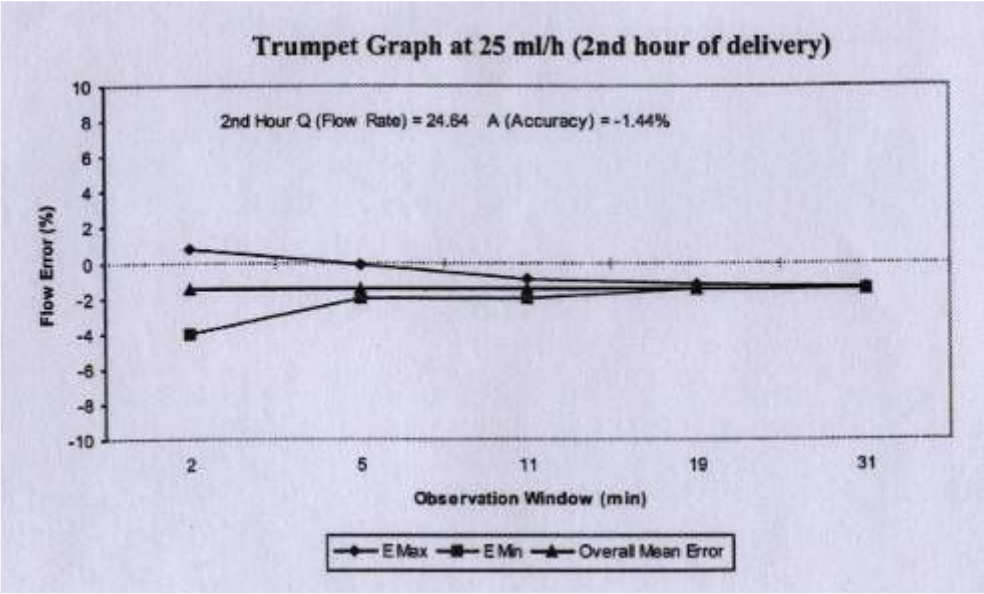
Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods or “Observation windows”, not continuous data versus operating time. Over long observation windows, short-term fluctuation has little effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effects as represented by the “mouth” of the trumpet.

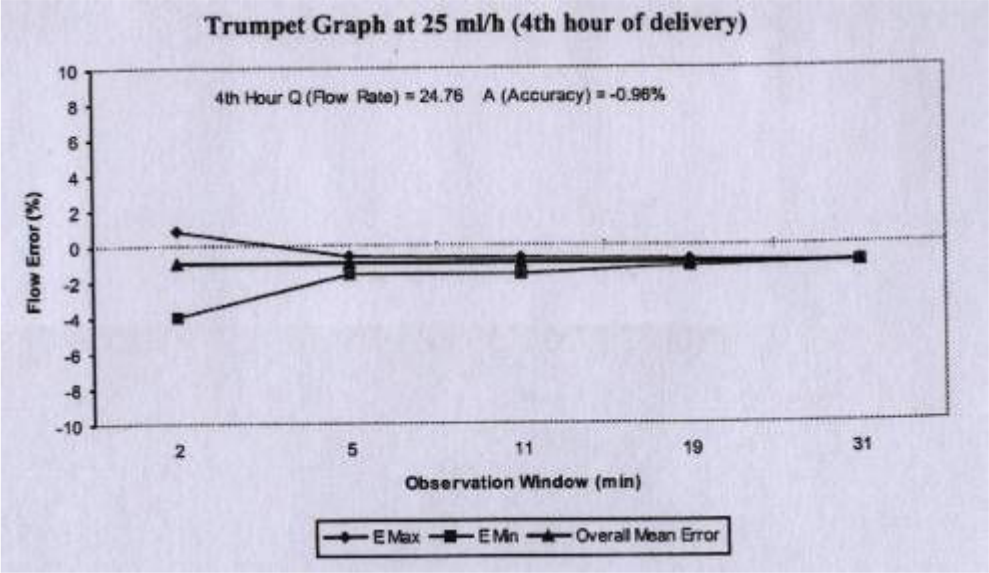
Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short-term fluctuations in rate accuracy may have clinical impact depending on the shelf life of the drug being infused and the degree of inter-vascular integration. The clinical effect cannot be determined from the trumpet curves alone.






Start-up Graph at 25 ml/h (Initial Period)
Flow (ml/hr)
50
45
40
35
30
25
20
15
10
5
0
0
20
40
60
80
100
120
Time (min)


Trumpet Graph at 25 ml/h (2nd hour of delivery)
2nd Hour Q (Flow Rate) = 24.64 A (Accuracy) = -1.44%
Flow Error (%)
10
8
6
4
2
0
-2
-4
-6
-8
-10
2
5
11
19
31
Observation Window (min)
EMax
EMin
Overall Mean Error


Trumpet Graph at 25 ml/h (4th hour of delivery)
4th Hour Q (Flow Rate) = 24.76 A (Accuracy) = -0.96%
Flow Error (%)
10
8
6
4
2
0
-2
-4
-6
-8
-10
2
5
11
19
31
Observation Window (min)
E Max
E Min
Overall Mean Error

2 – Symbols, Warnings and Cautions

System Symbols

The following symbols are used on the BodyGuard Infusion System and components. Labels on the system or statements in this manual proceeded by any of the following words and/or symbols are of special significance and are intended to help you to operate the pump in a safe and successful manner.

Attention, consult accompanying Instructions

CE mark indicates conformance to Medical Device Directive 93/42/EEC

Do not dispose of in municipal waste. Symbol indicates separate collection for electrical and electronic equipment. (WEEE Directive 2002/96/EEC). **NOTE**: Does not apply to the battery.

Do not dispose of battery in municipal waste. Symbol indicates separate collection for battery is required.

The use of single-use disposable components on more than one patient is a biological hazard. Do not reuse single-use disposable components.

Type CF applied part

Date of Manufacture

SN

Serial Number

Expiry Date of disposable

LOT

Lot Number

STERILE	EO

Sterilized with Ethylene Oxide

Terms Used In Manual

Warning: Indicates that the information is a warning. Warnings advise you of circumstances that could result in injury or death to the patient or operator.
Read and understand this manual and all warnings completely before operating the *BodyGuard* Infusion System.

Caution: Indicates that the information is a caution. Cautions advise you of circumstances that could result in damage to the device.
Read and understand this manual and all cautions completely before operating the *BodyGuard* Infusion System.

☞ NOTE: Indicates that the information that follows is additional important information or a tip that will help you operating the *BodyGuard* Infusion System.

Intended Use

The *BodyGuard* infusion Pump system is designed for infusion of medications or fluids requiring continuous or intermittent delivery at precisely-controlled infusion rates through clinically acceptable routes of administration, including intravenous, subcutaneous, percutaneous, intra-arterial, epidural, enteral, in close proximity to nerves, and into an intraoperative site (soft tissue/body cavity/surgical wound site). The system is intended for patients who require maintenance medications, analgesics, PCA therapy, parenteral and enteral nutrition fluids, chemotherapeutic agents and general fluids therapy in hospital and home care environments.

Warnings

To avoid possible personal injury or loss of life, observe the following:

Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary. Please contact your technician in order to enable the air sensor if disabled with no need.

Read the entire Operation Manual before using the pump, since the text includes important precautions.

The maximum volume that may be infused under SINGLE FAULT CONDITION is 0.1 ml

Voltage present on internal components may cause severe shock or death upon contact. Disconnect the Charger from the mains, prior to opening the casing. Only trained service personnel should open the pump cover.

Blown fuses could cause a fire hazard. Replace blown fuses on the Charger only with fuses of the same type and rating (see fuse values on the Charger PCB).

Boluses will be infused up to the full volume that is requested unless the user stops the bolus manually by pressing

. This is true even when the volume infused is less than the specified Hour Limit for Volume (e.g. 4 Hr Limit) at the beginning of a bolus and goes over the limit during the bolus (to complete it).

Make sure the pump is attached securely to the Charger, which is connected firmly to an IV pole.

A kinked or occluded IV line may impair the operation of the pump and the accuracy of the infusion. Before operation, verify that the IV line is not kinked or occluded.

The *BodyGuard* should be operated only with the *Bodyset* IV lines. Use of IV lines other than the *Bodyset* may impair the operation of the pump and the accuracy of an infusion.

Drugs must not be administered to the epidural space unless the drugs are indicated for this purpose and are administered in accordance with the indications included in the manufacture's package. Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient. For epidural administration of drugs use *MicroSet* only.

Any adjustments, maintenance, or repair of the uncovered pump may impair the operation of the *BodyGuard* Infusion System and/or the accuracy of the infusion. Any adjustments, maintenance, or repair of the uncovered pump or charger should be performed by authorized skilled technicians. Any adjustments, maintenance, or repair of the uncovered pump or charger while connected to the power should be avoided.

The *BodyGuard* Infusion System should be operated within a temperature range of 18°C (59°F) to 45°C (113°F) and up to 85% humidity. Operating the pump at temperatures and/or humidity other than within that range may affect accuracy.

Unsafe operation may result from using improper accessories. Use only accessories and options designed for this system.

Disposables must be compatible with the medicine delivered.

Battery charging is enabled as long as the charger cord is connected to the mains and the pump is in the charger. Switching the pump off does not disconnect it from the mains. To disconnect from mains, remove the charger cord from mains. To disconnect pump from mains, remove it from the charger.

Dropping the *BodyGuard* Infusion System could cause damage to components. If the pump is dropped, return the pump for inspection by qualified service personnel.

Use aseptic technique. Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components and do not re-use single use IV sets.

Watch your fingers and nails when opening the pump door.

When operating the pump on PCA program with a rate of 0.0 ml/h there is a hazard of blood clot forming. Connect saline infusion in parallel to avoid this problem.

When operating the pump on PCA program, the program will not enter KVO, even if the limit volume is acceded. The program will complete the bolus and than enter KVO.

Do not operate the pump near high-energy radio-frequency emitting equipment, such as electro-surgical cauterizing equipment. False alarm signals may occur.

Do not let the pump operate when battery is fully depleted. Pump may turn off during operation on fully depleted battery without alarm.

Never operate the pump without performing the battery test as described in chapter 4 in this manual.

Do not use the BodyGuard 323 for infusion of Insulin or for infusion of blood.

Cautions

To avoid possible damage to the equipment, observe the following:

Leaving the battery in a depleted state for a long period of time may damage the battery. Connect the pump to the mains via the Charger whenever possible to recharge the battery.

Do not store the pump with the battery fully depleted.

Xylene, Acetone or similar solvents could cause damage to components. Do not clean the pump with these chemicals. Clean solution spills on the pump immediately. Use a damp cloth or sponge. A mild detergent may be used. Wipe thoroughly with a dry cloth.

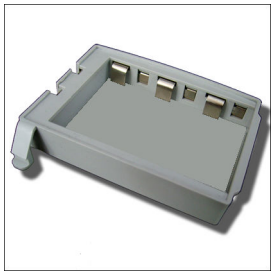
Immersing the *BodyGuard* Infusion pump into liquid could cause damage to components. Do not immerse the pump into any type of liquid.

Battery damage could occur if left in a temperature warmer than 50^0C (122°F).

3 – Installation and Set up

Unpacking

1. Carefully remove the pump and Charger from the box.
2. Make sure no items were damaged during shipment
3. Make sure you have the following items:
   - *BodyGuard* Infusion Pump
   - Charging Cradle with Power Cord or Battery Charging Cable
   - Rechargeable Battery Pack
   - Operation Manual
   - PCA bolus cable (optional)
   - 9V Alkaline Battery compartment (optional)
   - Disposable Battery Pack (optional)



   - External charger (optional)

   - Extended life battery Li-Ion Polymer 3600 mAh (optional)
   - External wall charger (Optional)

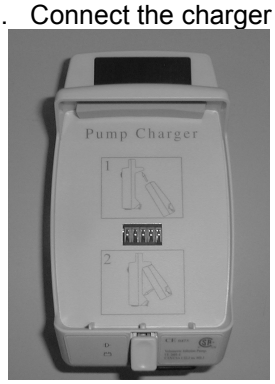
If any items are missing or damaged, contact your *BodyGuard* supplier.

Charging the Pump

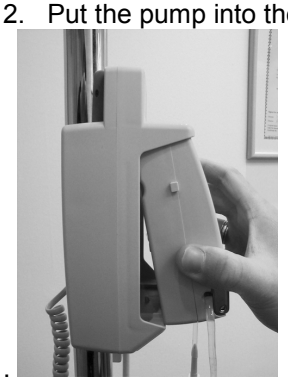
☞ NOTE: The pump is protected against overcharging. In order to keep your battery fully charged, connect the pump to the mains via the Charger whenever possible. Be sure that the battery is fully charged at all times.

⚠ **Warning:** If the battery is removed during operation while pump is not connected to a charger connected to mains, the pump will turn off.

1. Connect the charger unit to AC power and verify that the AC indicator is lit.



2. Put the pump into the charger (top first) until it clicks into place.



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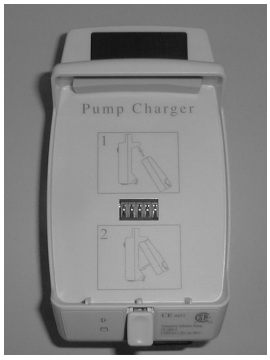
3. The battery is charging when the red battery LED on the front of the charger is lit. The battery is fully charged when the battery LED symbol turns green. If the led does not light or does not turn green after more than 8 hours, pls. replace battery.
4. Remove the pump from the charger by pressing the release button (located next to the LED indicators on the charger) and lift the pump out of the charger bottom first.



⚠ **Caution:** Leaving the battery fully depleted for a long period of time may damage the battery.

4 – Operation

Before Operating the Pump

Before attaching the system to a patient, run the following tests to verify that all indicators and alarms work properly.

When an alarm is activated the following occurs:

- An alarm message appears on the display
- An audible alarm sounds
- Infusion ceases
- The LED changes from green to red

☞ NOTE: All tests should be performed in the Continuous program.

Pump Operation Test

1. Click the pump into a Charger connected to AC power. Verify that the CHARGE indicator is on, Red or Green light (on charger).

2. Insert a BodySet administration set and close the door. Press the door until a click is heard.

☞ NOTE: For instructions on how to load and prime an administration set refer to sections “Loading the Administration Set” & “Priming the Line”.

3. Press

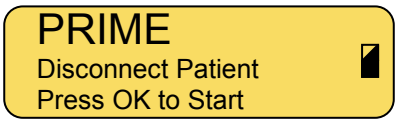
until the Self-Test screen appears. If air sensor is off, press

to confirm.

4. The program selected and its status are displayed. During the Self-Test a long beep will be heard. This procedure verifies that the pump’s acoustic and visual features are working properly. After self test is completed, the display will show the last rate setting.

5. Press

to prime the IV line.

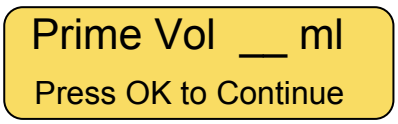


Warning: Ensure the set is not connected to a patient!!

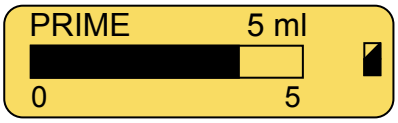
6. Enter the Volume of fluid required to prime the set and press

to begin priming procedure. You may stop priming at any time by pressing

.



7. The display screen will show a graph indicating the prime operation.



8. When priming is completed, wait 2 minutes without pressing any key. After two minutes the screen displays "Pump Unattended" and an alarm will sound. Press STOP NO to silence the alarm again or START OK to exit alarm condition.

Air in Line – Alarm Test

1. Insert a BodySet administration set and close the pump door. Press the door until a click is heard.

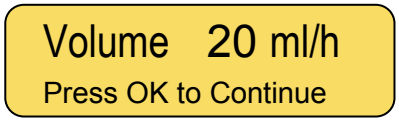
☞ NOTE: For instructions on how to load and prime an administration set refer to sections "Loading the Administration Set" & "Priming the Line".

2. Press ON OFF until the Self-Test Screen appears. If air sensor is off, press START OK to confirm. Please contact your technician in order to enable the air sensor if disabled with no need.

3. The pump displays the program selected and its status. The display will automatically change to display the last rate setting.

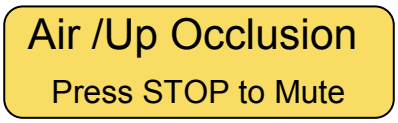
4. Change the infusion mode to Continuous (See "Change Set up" Section for instructions). Set the infusion rate at 500ml/hr, using the Numeric keypad and press START OK to confirm setting.

5. Set Volume at 20 ml and press START OK to start operation.



6. Insert air into the IV line to allow an air bubble greater than 10 mm to enter into the administration set.

7. Air in line alarm will be activated as soon as the air bubble enters the set segment located behind the pump door. Press STOP NO to turn the alarm off.



Down Occlusion – Alarm Test

1. Insert a BodySet into the pump and close the door. Press the door until a click is heard.
2. Make sure room temperature is 21-23 °C

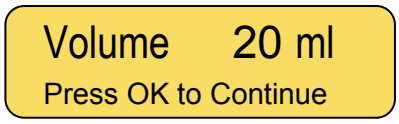
☞ NOTE: For instructions on how to load and prime an administration set refer to sections "Loading the Administration Set" & "Priming the Line".

3. Press ON OFF until the Self-Test screen appears. If air sensor is off, press START OK to confirm. Please contact your technician in order to enable the air sensor if disabled with no need.

4. The pump displays the program selected and its status. The display will automatically change to display the last rate setting.

5. Change the infusion mode to Continuous (See “Change Set up” Section for instructions). Set the infusion rate at 500 ml/hr using the Numeric keypad and press START OK.

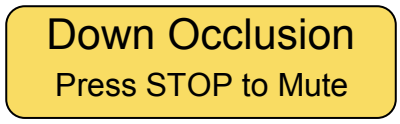
6. Set Volume at 20 ml and press START OK to start operation.



7. Wait 5 minutes and than connect a pressure gauge at a distance of 1 meter from the exit of the pump. Place both the pump and the pressure gauge at the same level (on a table)
8. Wait another 5 minutes and occlude the IV line downstream of the pump (between the pump and the pressure gauge).
9. The Down Occlusion alarm occurs at the time and rates listed below (time is measured from actual occlusion time to alarm, with accuracy of +30% -20%):
   - 500 ml/h up to 20 seconds
   - 60 ml/hr up to 1 minute
   - 1 ml/hr up to 80 minutes
   - 0.1 ml/hr up to 11 hours

☞ NOTE: The pressure threshold can be changed to suit patient need (refer to section on changing the current default Pressure Limit).

10. Depending upon the set flow rate and pressure threshold, the Down Occlusion alarm will be activated.
11. Press STOP NO to mute the alarm.

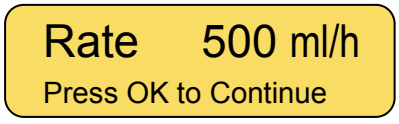


Door Open – Alarm Test

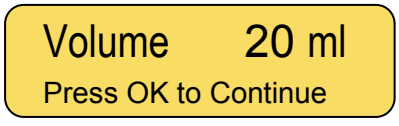
1. Insert a BodySet in the pump and close the door. Press the door until a click is heard.

☞ NOTE: For instructions on how to load and prime an administration set refer to sections “Loading the Administration Set” & “Priming the Line”.

2. Press ON OFF until the Self-Test screen appears. If air sensor is off, press START OK to confirm. Please contact your technician in order to enable the air sensor if disabled with no need.
3. The pump displays the program selected and its status. The display will automatically change to display the last rate setting.
4. Change the infusion mode to Continuous (See “Change Set up” Section for instructions). Set the infusion rate at 500ml/hr using the Numeric keypad and press START OK.



5. Set Volume at 20 ml press START OK to start operation.



6. Open the pump door.
7. Door Open alarm will be activated at once.

8. Close the door and press START OK.

Battery Test

1. Insert a BodySet in the pump and close the door. Press the door until a click is heard.

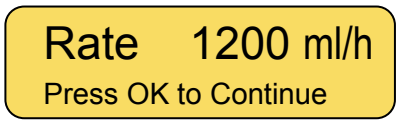
☞ NOTE: For instructions on how to load and prime an administration set refer to sections "Loading the Administration Set" & "Priming the Line".

2. Take the pump out of the charger.

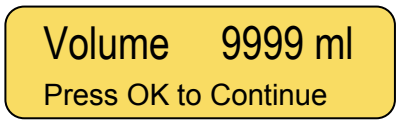
3. Press ON OFF until the Self-Test screen appears. If air sensor is off, press START OK to confirm. Please contact your technician in order to enable the air sensor if disabled with no need.

4. The pump displays the program selected and its status. The display will automatically change to display the last rate setting.

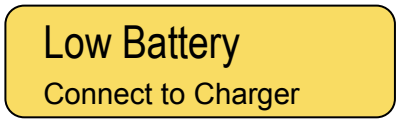
5. Change the infusion mode to Continuous (See "Change Set up" Section for instructions). Set the infusion rate at 1200 ml/hr using the Numeric keypad and press START OK.



6. Set Volume at 9999 ml and press START OK to start operation.



7. Wait untill pump displays "low battery" message



8. Press ON OFF to turn the pump off.

9. Connect the pump to a charger.

10. Verify the red icon of battery is lit (on the charger).

11. Verify the red battery turns green after a **minimum** of 2 hours.

WARNING: Do not let the pump operate when battery is fully depleted. Pump may turn off during operation on fully depleted battery without alarm.

Charger Indicator Test

1. Click the pump into the charger and connect the Charger to mains. Disconnect the power cord from the AC power outlet.

2. Verify that the CHARGE indicator is OFF.

3. Connect the power cord to the AC power outlet. Verify that the CHARGE indicator is ON.

Dedicated BodyGuard Administration Sets

The *BodyGuard* Infusion System should be operated only with *BodySet* dedicated Infusion sets.

Warning: Do not operate the *BodyGuard* Infusion System with any administration set, other than the *BodySet*. The *BodySet* Infusion Sets are equipped with a free flow protection valve, to prevent a gravity free flow hazard. Using a different set may essentially change the delivering rate and expose the patient to a free flow, which can cause serious injury or even death.

Warning: Using the pump with air in line detector off, may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary. Please contact your technician in order to enable the air sensor if disabled with no need.

The BodyValve

The Anti-Free Flow valve, BodyValve, enhances pump functioning by:

- Preventing free-flow in the event the set is detached from the pump.
- Preventing back-flow (reflux) in the event several infusion pumps are connected simultaneously to the same patient.
- Preventing free-flow in the event of a mechanical malfunction.
- Preventing pump operation if the set has been loaded incorrectly.

Warning: Replace the administration set every 72 hours to lessen the incidence of bacteria formation.

Warning: Disposables must be compatible with the medicine delivered.

Warning: Patient or operator injury may result if package is opened or damaged, or if damaged components are used. Visually inspect contents and package before each use.

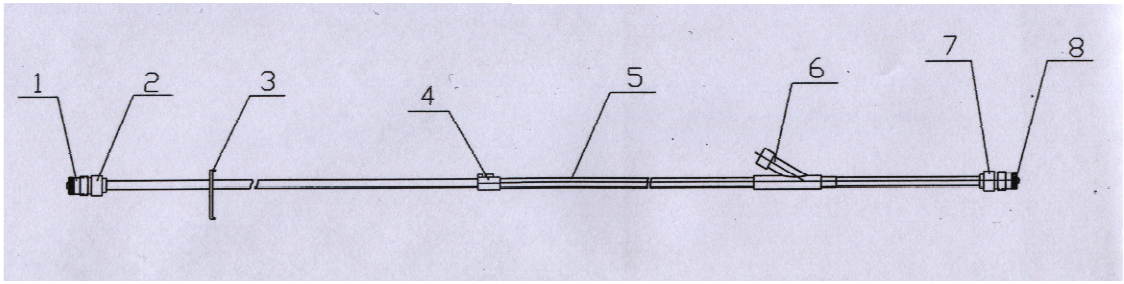
Warning: Air embolization can cause death or serious injury to the patient. Do not connect a patient to the BodyGuard Infusion Pump until all trapped air has been cleared from the fluid path. Carefully read the instructions for loading. Puncturing set components may cause air embolism.

Warning: Drugs must not be administered to the epidural space unless the drugs are indicated for this purpose and are administered in accordance with the indications included in the manufacture's package insert accompanying the drugs.
Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.

Warning: For epidural administration of drugs use BodySet microbore with yellow stripes on the tubing.

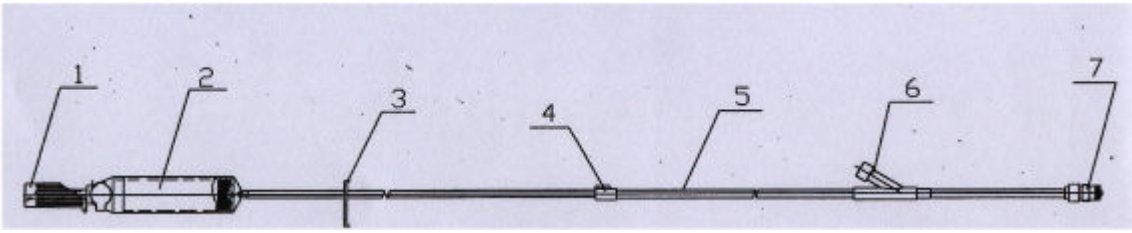
Caution: Component damage may occur if not installed properly. Assure all connections are secure; do not overtighten. This will help minimize leaks, disconnection and component damage.

The BodySet Macrobore



#	Area	Function
1	Luer Female Cap	Keeps the set sterile
2	Luer Female	Connects the administration set to solution bag
3.	Slide Clamp	Can be used to occlude the tube
4.	Key	Locates the tube in the correct flow direction
5.	Administration Tubing PVC 3 x 4.1 mm.	Transfers the solution
6.	Y Connector	Used to add drugs by syringe
7.	*BodyValve* With Cap	Anti free-flow valve
8.	Valve Cap	Keeps the set sterile

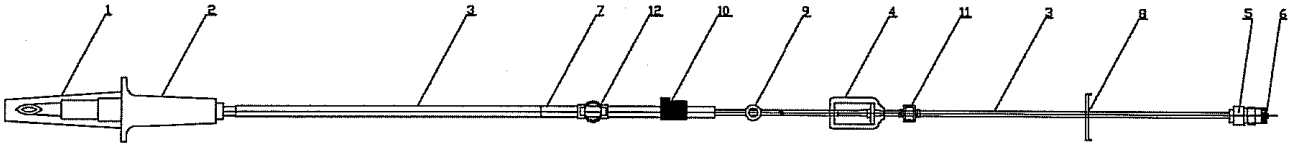
BodySet Macrobore with Drip Chamber



#	Area	Function
1	Spike With Cap	Connects the administration set to solution bag
2	Drip Chamber	Displays infused drops from the administration bag to the patient
3.	Slide Clamp	Can be used to occlude the tube
4.	Key	Locates the tube in the correct flow direction
5.	Administration Tubing 3 x 4.1 mm	Transfers the solution
6.	Y Connector	Used to add drugs by syringe
7.	*BodyValve* With Cap	Anti free-flow valve

* The set can be configured without the Y connector.

The BodySet Microbore



#	Area	Function
1.	Spike Cap	Keeps the set sterile
2.	BodySet Spike	Connects the administration set to solution bag
3.	Administration Tubing 1.5 x 3 mm	Transfers the solution
4.	Filter 1.2 micron	Filters the fluid path from air and particles
5.	Male luer lock	Connects the administration set to the patient access device
6.	Male luer lock Cap	Keeps the set sterile
7.	Administration Tubing 3x 4.1 mm	Transfers the solution (pumping segement)
8.	Slide clamp	Can be used to occlude the tube
9.	Prime valve	Anti free- flow valve with manual priming button
10.	Key	Locates the tube in the correct flow direction
11.	One way valve	Prevents free flow and back flow
12.	Anti Stretch locator	Prevents incorrect tube stretching and locates the administration set correctly

Loading the Administration Set

☞ NOTE: Follow the instructions supplied with the individual administration set.

⚠ **Warning:** Use of any administration set, other than the *BodySet*, may impair the operation of the pump and the accuracy of the Infusion.

1. Connect the administration set to the medication bag/
2. Lift the door latch (on the right side of the door) to open the *BodyGuard* pump door and remove the administration set from the sterile packaging leaving the end caps on the line.

   Connect the administration set to the medication bag.
3. Hold the section of tubing with the key (small plastic block) and make sure the flow direction is in line with the flow direction arrows inside the pump door.
4. Insert the IV tubing into the pump by placing the key into the keyway as shown by the arrow in diagram 1. Insert the tubing from left to right with the shorter end connected to the medication bag on the left , and avoid stretching or pulling the tubing. Check that the key located on the tube is located in its correct position in the tubing guide.

☞ NOTE: The IV key can only be fitted into the key space one way. If you are having trouble fitting it do not force it in. Try to turn the line around to ensure you have correctly lined up with the direction of flow.

5. Locate the Anti-Stretch locator in the round space on the left side.
6. Verify that the distal flow valve is on the right hand side of the pump.
7. Close the pump door until the catch clicks.

☞ NOTE: Ensure that the tubing is inserted completely into the pumping channel.

⚠ **Warning:** Use aseptic technique. Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components and use only once single use consumables marked ⊗ .

Priming the Line

☞ NOTE: *The BodySet* administration set contains a one-way check valve. Therefore, the lines cannot be primed using gravity and must be primed either using the *BodyGuard* pump priming function or by pressing on the manual priming valve.
In case manual priming is required, use an administration set with special manual priming valve.

Prime function is used:

1. Before starting a program
2. After air in line alarm

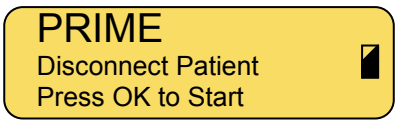
⚠ **Warning:** Always disconnect IV tubing from patient before starting priming procedure.

☞ NOTE: The default priming flow rate is 600 ml/hr. During priming, the air in line alarm is disabled.

Prime – In Continuous, Intermittent, TPN , and 25 Steps Modes

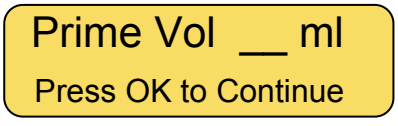
☞ NOTE: Access to the priming procedure in PCA mode is different from all other programs. For detailed instructions, refer to PCA Operation section.

1. Turn on the BodyGuard Pump, by pressing ON OFF until the Self-Test screen appears. If air sensor is off, press START OK to confirm.
2. When the display screen shows the existing programmed rate press PRIME BOLUS once.



⚠ **Warning:** Ensure the set is not connected to the patient!!

3. Enter the Volume of fluid required to prime the set and press START OK to begin priming procedure. You may stop priming at any time by pressing STOP NO.



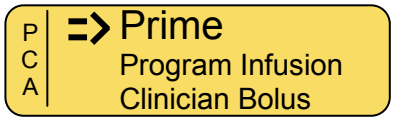
4. The display screen will show a graph indicating the prime operation.

5. Once the priming is completed, the display will change back to the previous screen the pump was in before priming. If more priming is needed, repeat procedure.

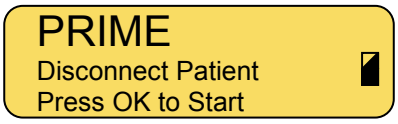
❖ Make sure that all air is removed from the IV line before connecting to the patient.

Prime – In PCA Mode

1. Turn on the BodyGuard Pump, by pressing ON OFF until the Self-Test screen appears. If air sensor is off, press START OK to confirm.
2. When the PCA menu displays, select “Prime” and press START OK to confirm.

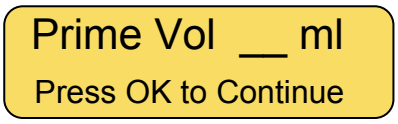


3. Press OK to program priming procedure.

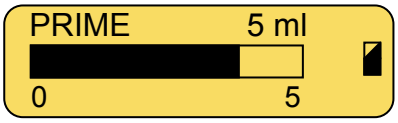


Warning: Ensure the set is not connected to the patient!!

4. Enter the volume to prime the set and press START OK to begin priming procedure. You may stop priming at any time by pressing START OK.



5. The display screen will show a graph indicating the prime operation.

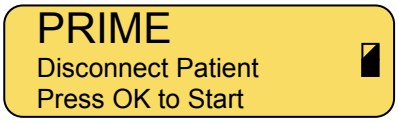


6. Once the priming is completed, the display will change back to the previous screen the pump was in before priming. If more priming is needed, repeat procedure.

- Make sure that all air is removed from the IV line before connecting to the patient.

Prime Operation – After Air In Line Alarm

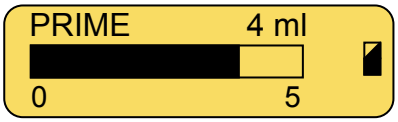
1. Press STOP NO to mute the alarm.
2. Disconnect IV tubing from patient.
3. Press PRIME BOLUS once.



Warning: Ensure the set is not connected to the patient!!

4. Enter the volume to prime the set and press START OK to begin priming procedure. You may stop priming at any time by pressing STOP NO.

5. The display screen will show a graph indicating the prime operation.



6. When priming is completed make certain that all air is removed from the IV line.
7. Connect IV line to the patient and press START OK to resume program.

Manual Prime Operation

1. In any case (before operation or after air in line alarm) a prime operation is needed, the user can prime the set manually by using the manual priming valve, if assembled in the administration set in use at that moment.
2. Disconnect IV tubing from patient.
3. Hold the tubing in a vertical position to maintain gravitation pressure. Press the priming valve button continuously until all trapped air is primed. Real ease the priming valve button to continue the anti free flow protection while infusing.

Operation steps

The following are the steps for starting the infusion procedure. For detailed instructions regarding each step, refer to the relevant sections in the Operation chapter.

Pump Mounted on IV Pole

1. Connect the *Bodyset* to the medication bag. Hang the bag on an IV pole.
2. Click the pump into the Charger. Mount the Charger on an IV pole.
3. Connect the Charger via a standard power cord to a grounded AC outlet.
4. Open the door of the pump and load the administration set into the pump's tubing guide.
5. Turn on the *BodyGuard* Pump, by pressing

until the Self-Test screen appears.

Warning: If air sensor is OFF, please contact your technician in order to enable the air sensor. Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

6. The program and status will appear on the display followed by the last rate setting.
7. Prime the administration set.

Warning: Make sure patient is not connected to the pump during priming!!

8. Set the required program and continue as described for every program setting.

Warning: Verify that infusion is proceeding normally before leaving the pump unattended.

Portable Connection

1. Connect the *Bodyset/MicroSet* to the medication bag.
2. Open the door of the pump and load the administration set into the pump's tubing guide.
3. Turn on the *BodyGuard* Pump, by pressing

until the Self-Test screen appears.

Warning: If air sensor is OFF, please contact your technician in order to enable the air sensor. Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

4. Prime the administration set.

Warning: Make sure patient is not connected to the pump during priming!!

5. Set the required program and continue as described for every program setting.

Warning: Verify that infusion is proceeding normally before inserting the bag and pump into the carrying bag.

Programming

The *BodyGuard* infusion System features five different programming options:

Continuous Program

- Rate: 0.1 to 100 ml/hr in 0.1 ml increments, and 100 to 1200 ml/hr in 1 ml increments
- Total Volume to be Infused: 0.1 to 9999 ml
- Program as Rate Over Volume or Volume Over Time
- Secondary Infusion (Piggy) Rate: 0.1 to 100 ml/hr in 0.1 ml increments, and 100 to 1200 ml/hr in 1 ml increments
- Secondary Infusion (Piggy) Volume: 0.1 to 9999 ml

Intermittent Program

- Used for setting a dose protocol at set intervals from 0.1 to 100 ml/hr in 0.1 ml increments, and 100 to 1200 ml/hr in 1 ml increments
- Volume: 0.1 to 9999 ml
- Interval Time: 0:01 minute to 20:00 hours

25 Steps Program

- Used for setting specific protocol that contains up to 25 steps
- Rate: 0.1 to 100 ml/hr in 0.1 ml increments, and 100 to 1200 ml/hr in 1 ml increments
- Volume: 0.1 to 9999 ml for each step
- Accumulated volume for all steps is up to ten liters

TPN Program

- Used for Total Parenteral Nutrition
- Volume: 1 to 9999 ml
- The program has a taper up/taper down pattern. The parameters to be set are: Total Volume, Time Up, Time Down and Total Time. The pump will calculate the ramping infusion rates.

PCA Program

- Used for PCA applications. Combines basal rate and pre-programmed boluses
- Rate: 0.0 to 100 ml/hr in 0.1 ml increments
- Volume: 0.1 to 1000 ml
- Bolus Volume: 0 to 100 ml
- Bolus Rate: 0.1 to 100 ml/hr in 0.1 ml increments, and 100 to 1200 ml/hr in 1 ml increments

Keep Vein Open Mode (KVO)

The *BodyGuard* Infusion System uses a Keep Vein Open (KVO) mode that can run at the end of every program, if desired. KVO also runs during a *delay* before an Intermittent program and during *Interval Time* in the Intermittent program. The KVO rate can be set from 0.1 to 5 ml/hr. If the programmed infusion rate is lower than the KVO rate, the KVO will run at the programmed infusion rate. KVO during *End Program* is limited to a volume of 5 ml.

☞ NOTE: To use the automatic KVO at the end of a protocol, make sure that the IV bag contains overfill beyond the volume to be infused.

End Program

When a protocol has completed, an audible alarm will beep 4 times. To stop the alarm and enter a new program, press

. If the stop key is not pressed before the 4 beep have concluded, KVO will begin when it is programmed to do so.

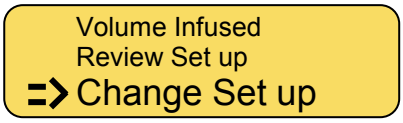
Changing Current Program – Using Level 1 Code

1. Turn on the BodyGuard Pump, by pressing ON OFF until the Self-Test screen appears.

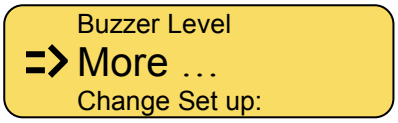
   If air sensor is OFF, please contact your technician in order to enable the air sensor if disabled. Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

2. When a programming screen or infusion summary is displayed, press Info twice.

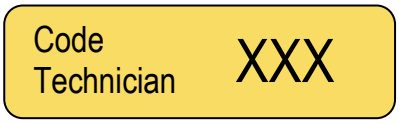
3. Scroll to "Change Set up" option. Press START OK.



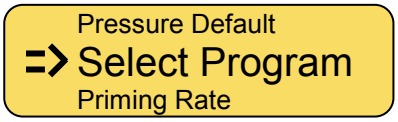
4. Scroll to "More …" and press START OK.



5. Enter *Change Set up* **Level 1** code, using the numeric keyboard and press START OK.

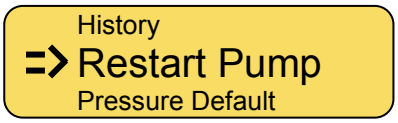


6. Scroll down to "Select Program" option and press START OK.



7. Scroll to the required program and press START OK.

8. Press START OK to restart the pump.



☞ NOTE: The selected program will remain in the pump's memory until changed by the operator.

Changing Current Program – Short Way

1. Turn on the BodyGuard Pump by pressing ON OFF until the Self-Test screen appears. If air sensor is OFF, press START OK to confirm.

2. Once the Self-Test is completed, immediately press and hold STOP NO for two seconds. The Program selection mode will be displayed.

3. Scroll to the required program and press START OK.

☞ NOTE: If the current selected program is **PCA**, the Short Cut option is not available.

Continuous Infusion

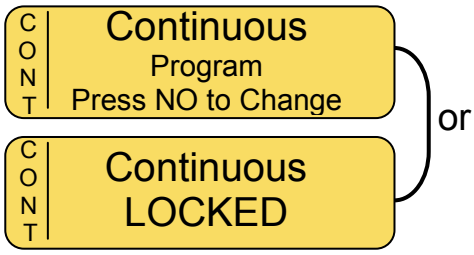
Rate Over Volume

1. Turn the pump ON by pressing and holding the ON OFF until the Self-Test screen appears.

   If air sensor is OFF, please contact your technician in order to enable the air sensor if disabled. Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

2. Pump displays program name and status. The status is either "Program" or "Locked" (for instruction regarding locking and unlocking the pump – refer to *Lock Mode* section).

   When unlocked, press START OK. Wait for the rate screen to display.



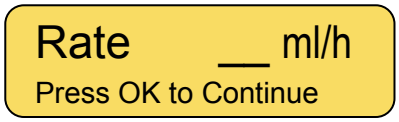
☞ NOTE: When pump is in *Program mode,* all parameters can be adjusted. When pump is in *lock out mode,* parameters can be viewed, but cannot be changed.

☞ NOTE: If pump is not in *Continuous* Program, refer to changing program section for instructions.

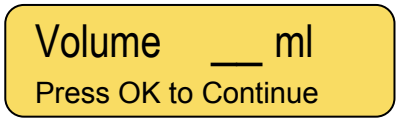
☞ NOTE: Whenever you decide to set a new program, follow instructions at the bottom of screen.

☞ NOTE: The screen will be blank upon initial setup. When returning to a program, the screen will display the last set program.

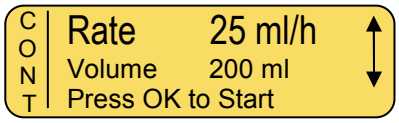
3. ***Rate Screen***
   Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the desired Rate and press START OK.



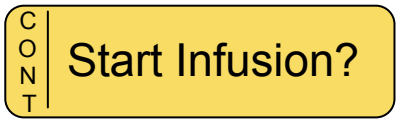
4. ***Volume Screen***
   Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the desired Volume and press START OK.



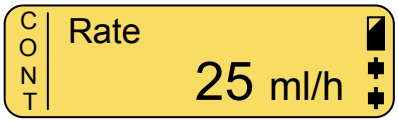
5. ***Accumulation Screen***
   Do one of the following:
   - Press START OK to confirm the existing parameters and start infusion.
   - Press STOP NO to go back to Rate screen.



6. Press START OK to Start Infusion.



7. During program operation, the pump displays the rate in which the program is operating.



☞ NOTE: If one of the values is changed during the programming mode, the pump will not recall the new value unless changes are confirmed by pressing START OK.

NOTE: If prime procedure is activated during data setting, the pump will return to the original (previous) screen once priming is completed.

Rate Titration

The pump allows rate titration during the *Rate Over Volume* Program.

To change the rate during the infusion:

1. Use numeric keypad to enter the new desired rate during operation and press START OK within five seconds.
The pump will briefly alarm and the infusion will resume at the adjusted rate.

☞ NOTE: If the rate change is not confirmed within ten seconds, the pump will continue operation at the original rate and the display will return to the previous setting.

2. To stop the infusion press STOP NO.

To change the rate while in Stop mode:

1. Press any number on the keypad twice to return to the rate screen.
2. Adjust the rate and press START OK.
3. Adjust the volume and press START OK three times to restart infusion.

☞ NOTE: During programming you may backspace by using STOP NO:

Pressing STOP NO once clears the last entered digit.

Pressing STOP NO again clears the next number.

Pressing STOP NO when the value is empty displays the original value or the previous screen.

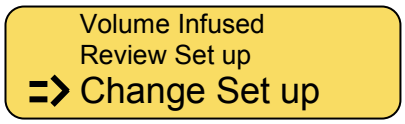
Volume Over Time

☞ NOTE: Before operating the pump in *Volume Over Time*, make sure that you are in the *Continuous* Program and that the IV bag contains an additional 5 ml of volume to be infused. This ensures adequate volume for KVO during *End Program*.

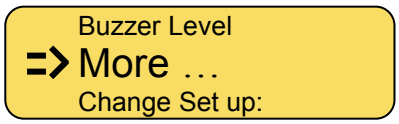
To set *Volume Over Time,* enable the time function by following the steps below:

1. Press twice.

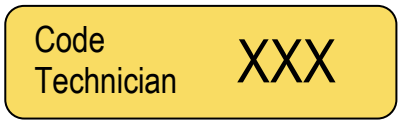
2. Scroll to "Change Set up" option. Press START OK.



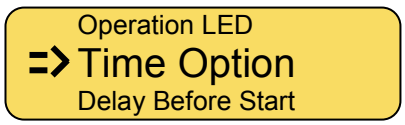
3. Scroll to "More …" and press START OK.



4. Enter *Change Set up* **Level 1** code, using the numeric keyboard and press START OK.



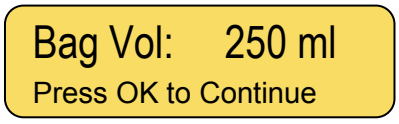
5. Scroll to "Time Option" option. Press START OK.



6. Press or , to turn Time Option ON.

7. Press START OK twice.

8. ***Volume Screen***
Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the desired volume using the numeric keypad and press START OK.

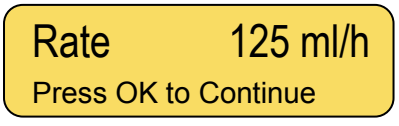


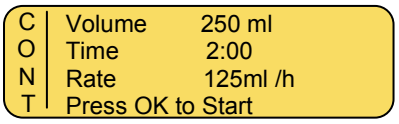
☞ NOTE: The screen will be blank upon initial setup.

9. ***Infusion Time Screen***
   - Enter the desired total time using the numeric keypad (for example enter 0-2-0-0 for two hours) and press START OK.

☞ NOTE: First two digits represent hours and last two digits represent minutes.

10. ***Rate Screen***
The pump calculates the rate based on the time and volume entered, and displays the rate on the screen. Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Press STOP NO to go back to volume setting screen.





11. During program operation, pump displays the rate at which the program is operating.

☞ NOTE: If one of the values is changed during the programming mode, the pump will not recall the new value unless changes are confirmed by pressing START OK.

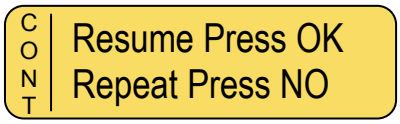
☞ NOTE: If prime procedure is activated during data setting, the pump will return to the original (previous) screen once priming is completed.

☞ NOTE: When required to stop infusion, press STOP NO. Stop will be displayed on the screen. Stop mode is limited for two minutes. After two minutes, alarm will sound. Press STOP NO to mute or START OK to continue.

Resume or Repeat Infusion

Unlocked
When the pump is restarted in Continuous mode and is not locked, the pump will allow the user to confirm each of the parameters of the infusion. The V*olume* will be adjusted for the amount infused prior to turning off the pump. To reset the volume, use the numeric keypad to enter new volume.

Locked
1. When the pump is turned OFF in the middle of an infusion, this screen will appear when the pump is turned back ON.



2. Do one of the following:

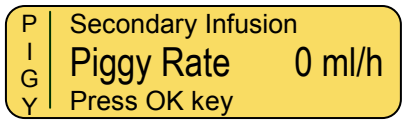
- **Resume:** To resume this program exactly where it stopped, press START OK. The accumulation screen is displayed. The volume remaining will be infused.
- **Repeat:** To restart the program at the beginning and or to set new parameters, press STOP NO and follow the instructions on the pump

Secondary Infusion (PIGGY) During Continuous Operation

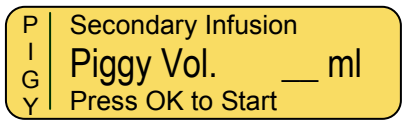
To perform a secondary infusion during Continuous operation, complete the following steps.

1. Press PRIME BOLUS once.

2. Enter Secondary Infusion Rate and press START OK.



3. Enter Secondary Infusion Volume and press START OK.



4. Pump will beep once and resume the Primary Infusion when the Secondary Infusion is completed.

☞ NOTE: User can stop the Secondary Infusion at any time by pressing STOP NO and turning the pump off. When the pump is turned back on, the pump will resume the Primary Infusion.

☞ NOTE: User can titrate the Secondary Infusion with the same method that is used for a primary continuous infusion.

Intermittent Infusion

The Intermittent Infusion program is a special program which enables the design of a dose delivery protocol at set intervals. Each dose is given at a set time. The pump will Keep Vein Open between the doses. The infusion program continues until the total volume to be infused is delivered.

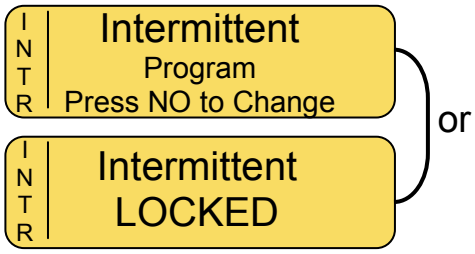
Rate Over Volume

1. Turn the pump ON by pressing and holding the ON OFF until the Self-Test screen appears.

   If air sensor is OFF, please contact your technician in order to enable the air sensor if disabled. Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

2. Pump displays program name and status. The status is either "Program" or "Locked" (for instruction regarding locking and unlocking the pump – refer to *lock* mode section).

   If pump is unocked, the Bag Volume screen will display after 2 seconds.



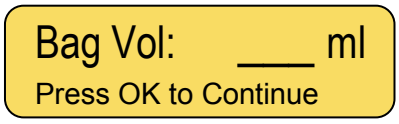
☞ NOTE: When pump is in *Program mode* all parameters can be adjusted; When pump is in *lock out mode,* parameters can be viewed, but cannot be changed.

☞ NOTE: If pump is not already in *Intermittent* Program, refer to Changing Program section for instructions.

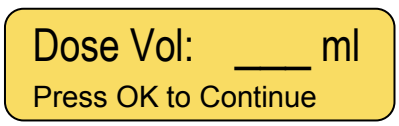
☞ NOTE: Whenever you decide to set a new program, follow instructions at the bottom of screen.

☞ NOTE: When returning to a program, the screen will display the last set program.

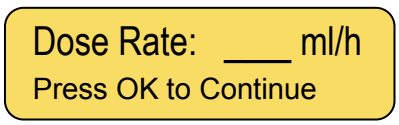
3. ***Bag Volume Screen***
   Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the Bag Volume and press START OK.



4. ***Dose Volume Screen***
   Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the Dose Volume and press START OK.



5. ***Dose Rate Screen***
   Do one of the following:
   - Press START OK to confirm the existing parameters
   - Enter the Dose Rate and press START OK.



6. ***Interval Time Screen***
Do one of the following:

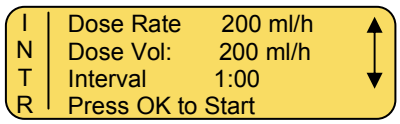
- Press START OK to confirm the existing parameters
- Enter the time between the start of each dose and press START OK.

☞ NOTE: Interval time is counted from starting time of one bolus until starting time of the following bolus.

7. ***KVO Rate Screen***
Do one of the following:

- Press START OK to confirm the existing parameters
- Enter the desired KVO rate (from 0.1 to 5 ml/h) and press START OK.

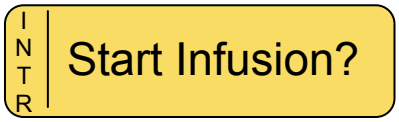
8. ***Accumulation Screen***
Do one of the following:



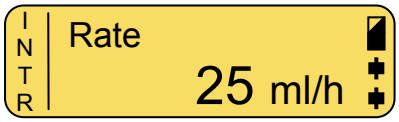
- Press START OK to confirm the existing parameters and start infusion.
- Press STOP NO to go back and adjust program parameters.

☞ NOTE: If pump is in **Delay Mode**, enter Start Time (24 Hour Clock) and Start Date. For further information regarding the Delay Option, refer to Delay Program section.

9. Press START OK to Start Infusion.



10. During program operation, the pump displays the rate in which the program is operating.



☞ NOTE: If one of the values is changed during the programming mode, the pump will not recall the new value unless changes are confirmed by pressing START OK.

☞ NOTE: If prime procedure is activated during data setting, the pump will return to the original (previous) screen once priming is completed.

☞ NOTE: Whenever required to stop infusion, press STOP NO. Stop displays on the screen. Stop mode is limited for two minutes. After two minutes an audible alarm is sounded. Press STOP NO again to mute the alarm.

Rate Titration

The pump allows rate titration during the *Intermittent* Program.

To change the rate during the infusion:

1. Use numeric keypad to enter the new desired rate during operation and press START OK within five seconds.
   The pump will briefly alarm and the infusion will resume at the adjusted rate.

☞ NOTE: If pump is LOCKED, the **Level 1** technician code must be entered to confirm the rate change.

☞ NOTE: Rate titration is allowed only during dose delivery and not during KVO between doses.

☞ NOTE: If the rate change is not confirmed within ten seconds, the pump will continue operation at the original rate and the display will return to the previous setting.

2. To stop the infusion press STOP NO.

To change the rate while in Stop mode:

1. Press any number on the keypad twice to return to the rate screen.
2. Adjust the rate and press START OK.
3. Adjust all other parameters and press START OK to restart infusion.

☞ NOTE: During programming, you may backspace by using STOP NO:

Pressing STOP NO once clears the last entered digit.

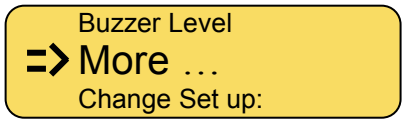
Pressing STOP NO again clears the next number.

Pressing STOP NO when the value is empty displays the original value or the previous screen.

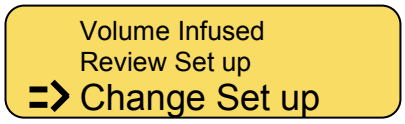
Volume Over Time

To program with Time and Volume instead of Rate and Volume, enable the Time Option function by following the steps below:

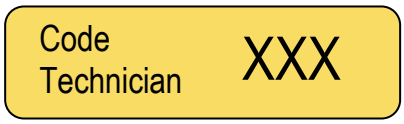
1. Press Info twice.
2. Scroll to "Change Set up" option. Press START OK.



3. Scroll to "More …" and press START OK.

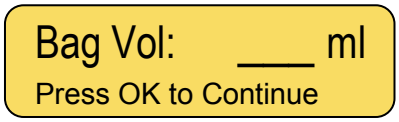


4. Enter *Change Set up* **Level 1** code, using the numeric keyboard and press START OK.

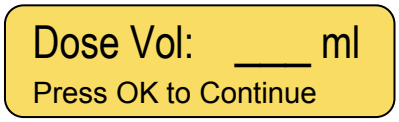


5. Scroll to "Time Option" option. Press START OK.

6. Press ▽0 or △2, to turn Time Option ON.
7. Press START OK twice.
8. ***Bag Volume Screen***
   Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the Bag Volume and press START OK.



9. ***Dose Volume Screen***
   Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the Dose Volume and press START OK.



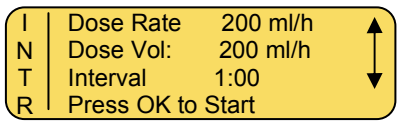
10. ***Dose Time Screen***
    Do one of the following:
    - Enter the Dose Time and press START OK.
      (To enter 30 minutes, press 0-0-3-0)

11. ***Interval Time Screen***
    Do one of the following:
    - Press START OK to confirm the existing parameters
    - Enter the time between the start of each dose and press START OK.

12. ***KVO Rate Screen***
Do one of the following:

- Press START OK to confirm the existing parameters
- Enter the KVO Rate (from 0.1 to 5 ml/h) and press START OK.

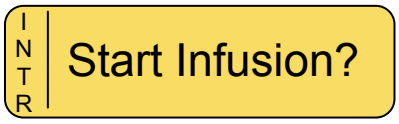
13. ***Accumulation Screen***
Do one of the following:



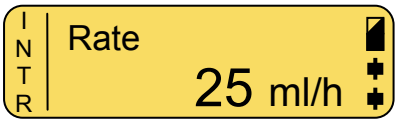
- Press START OK to confirm the existing parameters and start infusion.
- Press STOP NO to go back and adjust program parameters.

☞ NOTE: If pump is in **Delay Mode**, enter Start Time (24 Hour Clock) and Start Date. For further information regarding the Delay Option, refer to Delay Program section.

14. Press START OK to Start Infusion.



15. During program operation, the pump displays the rate in which the program is operating.

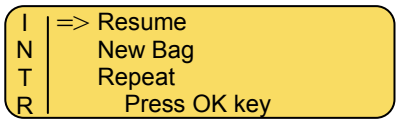


Resume Infusion, Start New Bag, or Restart Infusion

When an Intermittent infusion is unlocked and stopped and the pump is re-started, the user has the following options:

(1) **Resume:** Resume the original infusion exactly where it left off
(2) **New Bag:** Resume the original infusion with a new bag
(3) **Repeat:** Repeat or re-program the infusion

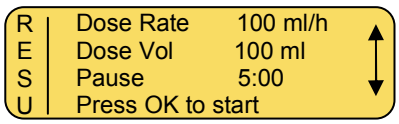
1. ***Intermittent Restart Screen***



Press 0 or 2 to scroll to the appropriate selection and press START OK.

☞ NOTE: If pump is Locked, the user will only have the “Resume” and “New Bag” options available.

2. ***Resume – New Bag – Restart Screen***
Display shows a summary of the current infusion to be started. User can scroll through the details by pressing 0 or 2. Press START OK to start infusion.



Program Delay

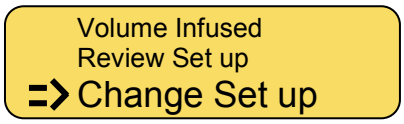
The option to Delay Program Before Start can only be used in the Intermittent Mode.

Turning the Delay Option ON

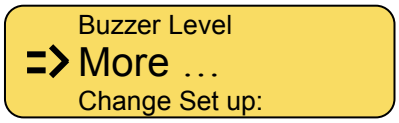
1. Press twice from STOP or setting mode.

Warning: If air sensor is off, please contact your technician in order to enable the air sensor if disabled. Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

3. Scroll to "Change Set up" option and press START OK.



4. Scroll to "More …" and press START OK.



5. Enter *Change Set up* level 1 code, using the numeric keyboard and press START OK.

6. Scroll to "Delay Before Start" option and press START OK.

6. Turn delay option ON by pressing or .

7. Press START OK and the screen displays Restart Pump

8. Press START OK to continue.

Setting Delay Before Start

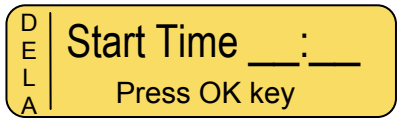
After entering the program data, the pump enables delay setting (when *Delay Before Start* is turned ON).

☞ NOTE: The delay time is set according to a 24 hour clock. This means that hours are viewed as follows 10:00, 11:00, 12:00, 13:00, 14:00, 15:00 etc.

☞ NOTE: The pump automatically displays the current time and date. To start pump immediately, press START OK to confirm the existing time and date and start infusion.

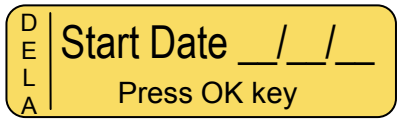
☞ NOTE: If the time and/or date automatically displayed by the pump are not correct, go to the *Settings Menu* and select *"Set Time & Date"* to reset the clock in the pump.

1. ***Start Time Screen***
To change the Start Time, type the desired start time using the numeric keypad and press START OK. To start pump immediately, do not change the time and press START OK.

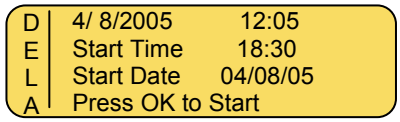


☞ NOTE: To start pump at **9:30 AM**, enter **0-9-3-0**. To start the pump at **9:30 PM**, enter **2-1-3-0**.

2. ***Start Date Screen***
To change the Start Date, type the desired start date using the numeric keypad and press START OK. To start pump on the same day, do not change the date and press START OK.



3. ***KVO During Delay Screen***
During delay time, pump will operate in KVO mode. Time left will count down until 00:00 and will then automatically start the progrmamed infusion. During the delay, this screen will be displayed showing when the infusion will start.



☞ NOTE: After delay time, pump will beep once and infusion will start automatically.

Turning Pump Off In The Middle Of An Intermittent Infusion

When the pump is turned OFF during an intermittent infusion, the internal clock in the pump will continue to monitor the timing of the infusion.
If the pump is stopped during a dose, the user will be able to resume the dose if the infusion is resumed before one third of the interval time has elapsed. For example, if the interval is 4 hours, then the user can restart the infusion within 1 hour and 20 minutes of the interval time to receive the remainder of the dose. In this case, the pump will still resume the following dose at the scheduled time. If the user restarts the infusion after one third of the interval time has elapsed, then the user will not be receive the remainder of the dose. The pump will resume in the middle of the interval and receive KVO until the next dose is due. The purpose of this “One Third” rule is to allow the user to turn their pump off during a dose without changing the scheduled dose times.

If the pump is turned off during a dose and not restarted until after the next scheduled does was scheduled, then the pump will start the next dose immediately followed by a complete interval. For example, if the patient restarts the infusion an hour past the scheduled dose time, then will receive a complete dose followed by a complete interval.

If the pump is turned off during the interval period, the patient can restart the pump anytime before the next scheduled dose without impacting the timing of the delivery of the next dose. If the pump is not restarted until after the next scheduled does was scheduled, then the pump will start the next dose immediately followed by a complete interval.

25 Steps Protocol

This protocol permits programming of up to twenty-five different steps. Each step has its own rate and volume. Step accumulation is limited to a Volume of ten (10) liters. Protocol steps are delivered sequentially until all steps are completed.

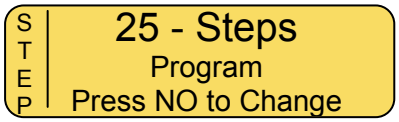
☞ NOTE: Before operating the pump in *25 Steps Protocol*, make sure that the IV bag contains an additional 5 ml of total volume to be infused. This ensures adequate volume for KVO during *End Program*. If *Delay Before Start* is set, you must include enough volume for the delay period, in addition to the 5 ml KVO volume.

1. Turn the pump on by pressing and holding the ON OFF until the Self-Test screen appears.

Warning: If air sensor is OFF, please contact your technician in order to enable the air sensor if disabled. Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

2. Pump displays program name and status. The status is either "Lock out" or "program" (for instruction regarding locking and unlocking the pump, refer to *locking* section).

   When the pump is unlocked, press START OK to continue.



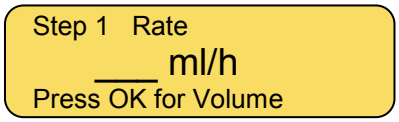
☞ NOTE: When pump is in *Program mode*, all parameters can be adjusted; When pump is in *lock out mode*, parameters can be viewed, but cannot be changed.

☞ NOTE: If pump is not already in *25 Steps Protocol*, refer to changing program section for instructions.

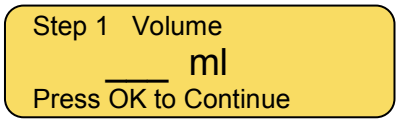
☞ NOTE: Whenever you decide to set a new program, follow instructions at the bottom of screen.

☞ NOTE: The screen will be blank upon initial setup.

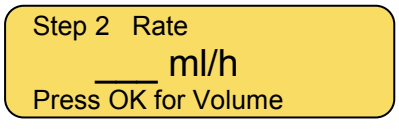
3. ***Rate Screen – Step 1***
   Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the desired rate and press START OK.



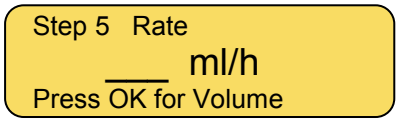
4. ***Volume Screen – Step 1***
   Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the desired volume and press START OK.



5. ***Rate Screen – Step 2***
   Pump displays the rate for step 2. Repeat directions as for step 1 and repeat until the required number of steps are entered.



6. After entering the last required step, press START OK without entering a rate.



This indicates that all data required for the protocol has been set. All programs following the last set program will be automatically cleared.

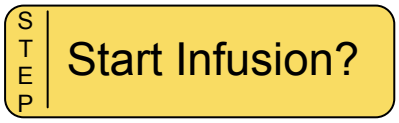
☞ NOTE: If pump is in **Delay Mode**, enter KVO rate.

7. ***Accumulation Screen***
Do one of the following:

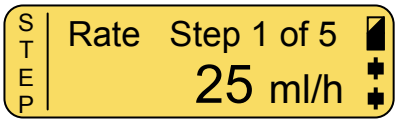
- Press START OK to confirm the existing parameters.
- Press STOP NO to go back to rate setting screen.

☞ NOTE: If pump is in **Delay Mode**, enter Start Time (24 Hour Clock) and Start Date. For further information regarding the Delay Option, refer to Delay Program section.

8. Press START OK to Start Infusion.



9 During program operation, the display identifies which step is currently running, and the rate.



☞ NOTE: If one of the values is changed during the programming mode, the pump will not recall the new value unless changes are confirmed by pressing START OK.

If prime procedure is activated during data setting, the pump will return to the original (previous) screen once priming is completed.

☞ NOTE: Whenever required to stop infusion, press STOP NO. Stop displays on the screen. Stop mode is limited for two minutes. After two minutes an audible alarm is sounded. Press STOP NO again to mute the alarm.

☞ NOTE: During programming you may backspace by using STOP NO.

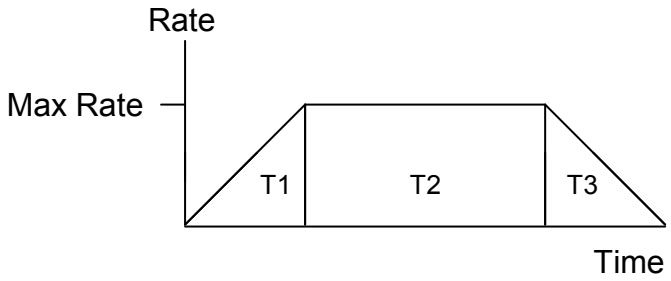
Pressing STOP NO once clears the last entered digit.

Pressing STOP NO again clears the next number.

Pressing STOP NO when the value is empty displays the original value or the previous screen.

TPN Infusion

Total **P**arenteral **N**utrition - This mode delivers an infusion while automatically tapering up and down. The pattern of the program is a trapezoid.



TPN Trapezoid Program

T1 = Time UP
T2= Time FLAT
T3= Time DOWN

On a TPN Program the operator may set the total volume which corresponds to the size of the bag to be infused, the total time, and the up and down time. Program operation will start from 2 ml/h and will increase to the maximal rate. During the flat session (T2) the rate will not change. During the last part of the program (T3), the program will start to decrease the infusion rate according to the set taper down time.

Up and down time can be set to zero. A TPN program with up and down time set to zero, is a **continuous** program.

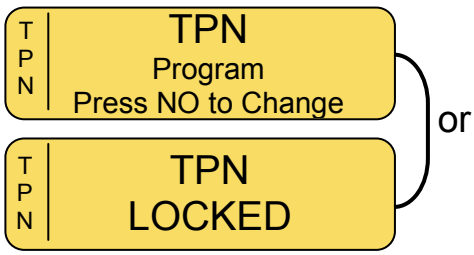
☞ NOTE: Before operating the pump in *TPN program*, make sure that the IV bag contains an additional 5 ml of total volume to be infused. This ensures adequate volume for KVO during *End Program*. If *Delay Before Start* is set, you must include enough volume for the delay period in addition to the 5 ml KVO volume.

1. Turn the pump on by pressing and holding the ON OFF until the Self-Test screen appears.

Warning: If air sensor is off, please contact your technician in order to enable the air sensor if disabled. Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

2. Pump displays program name and status. The status is either "Lock out" or "Program" (for instruction regarding locking and unlocking the pump – refer to *Lock Out* section).

When pump unlocked, press START OK to continue.



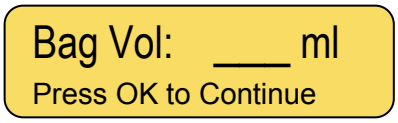
☞ NOTE: When pump is in *Program mode*, all parameters can be adjusted; When pump is in *lock out mode* parameters can be viewed, but cannot be changed.

☞ NOTE: If pump is not already in *TPN* Program, refer to changing program section for instructions.

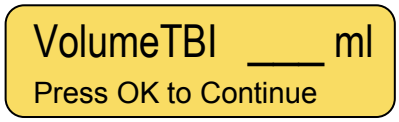
☞ NOTE: Whenever you decide to set a new program, follow instructions at the bottom of screen.

3. ***Bag Volume Screen***
Do one of the following:

- Press START OK to confirm the existing parameters.
- Enter the desired volume and press START OK.



4. ***Volume To Be Infused (TBI) Screen***
Do one of the following:

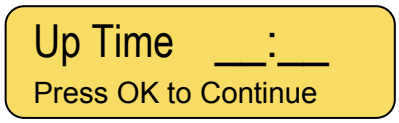


- Press START OK to confirm the existing parameters.
- Enter the desired volume and press START OK.

5. ***Total Time Screen***
The screen displays the last set time (total time for the program to run). Press START OK to confirm the existing parameters or enter the desired time and press START OK.

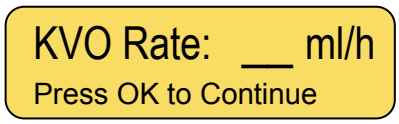
☞ NOTE: First two digits represent hours and last two digits represent minutes (for example, enter 0-2-0-0 for 2 hours.). Use a point to move from hours to minutes.

6. ***Up Time Screen***
The screen displays the time for rate to taper up. Press START OK to confirm the existing parameters or enter the desired value (from 00:00 to 04:15 hours). Press START OK.



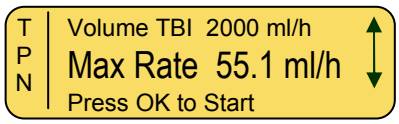
7. ***Down Time Screen***
The screen displays the time for rate to taper down. Press START OK to confirm the existing parameters or enter the desired value (from 00:00 to 04:15 hours). Press START OK.

8. ***KVO Rate Screen***
Do one of the following:



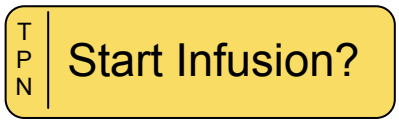
- Press START OK to confirm the existing parameters
- Enter the desired Interval Time and press START OK.

9. ***Accumulation Screen***
The pump calculates the set data and displays the accumulation screen with the maximal rate for the program (to be infused during flat period).
Do one of the following:

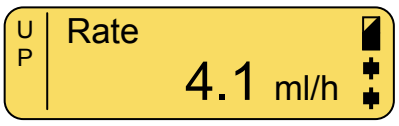


- Press START OK to confirm parameters and start infusion or enter delay time, if applicable. For further information regarding delay option, refer to delay program section.
- Press STOP NO to go back to volume setting screen.

10. Press START OK to start infusion.



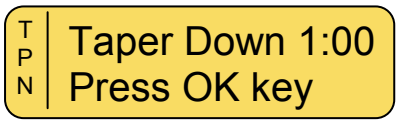
11. During program operation, pump displays the rate in which the program is operating and program direction (Up/Flat/Down).



Early Taper Down

If the program must be interrupted early and the planned taper down time must commence immediately, do as follows:

1. Press STOP NO continually (2 seconds) to stop the pump operation and display Taper Down screen.



2. Do one of the following:
   - Press START OK to start the taper down process immediately with the existing parameters.
   - Enter time for taper down, using the numeric keys, and press START OK to start the taper down process. Taper down time should be lower than the ongoing taper down time.

☞ NOTE: If one of the values is changed during the programming mode, the pump will not recall the new value unless changes are confirmed by pressing START OK.

☞ NOTE: If prime procedure is activated during data setting, the pump will return to the original (previous) screen once priming is completed.

☞ NOTE: Whenever required to stop infusion, press START OK. Stop displays on the screen. Stop mode is limited for two minutes. After two minutes, an audible alarm is sounded. Press START OK again to mute the alarm.

☞ NOTE: During programming you may backspace by using STOP NO:

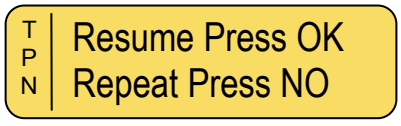
Pressing STOP NO once clears the last entered digit.

Pressing STOP NO again clears the next number.

Pressing STOP NO when the value is empty displays the original value or the previous screen.

Resume or Repeat Infusion

1. When the pump is turned OFF during infusion, this screen will appear when the pump is turned back ON.



2. Do one of the following:
   - **Resume:** To resume this program exactly where it stopped, press START OK. The accumulation screen is displayed. The volume remaining will be infused.
   - **Repeat:** To restart the program at the beginning and or to set new parameters, press STOP NO and follow the instructions on the pump

PCA Infusion

Patient Control Analgesia is a program used for patients who require IV pain management or epidural analgesia. Pain management is undertaken by delivering a continuous basal rate, in combination with pre-programmed boluses. The pump will deliver only the boluses corresponding to the preset time intervals. All attempts to obtain a bolus are stored in the pump memory. The physician can read these statistics and adjust the settings as required.

Warning: When operating the pump on PCA program with a rate of 0.0 ml/h there is a hazard of blood clot forming. Connect saline infusion in parallel to avoid this problem.

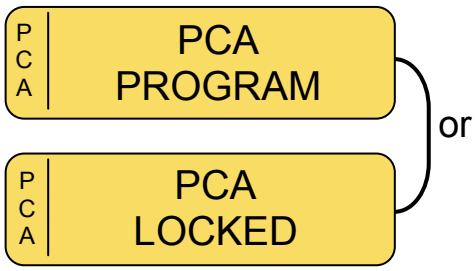
PCA Menu

Due to the sensitive nature of PCA infusions, the BodyGuard 323 has a specific menu to enhance the user experience while programming PCA infusions. The menu organizes the infusion information centrally while maintaining the same programming format as the other infusion modes on the pump.

1. Turn the pump on by pressing the ON OFF until the Self-Test screen appears.

Warning: If air sensor is OFF, please contact your technician in order to enable the air sensor. Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary.

2. Pump displays program name and status. The status is either "PROGRAM" or "LOCKED" (for instruction regarding locking and unlocking the pump – refer to *Unlocking PCA* section).



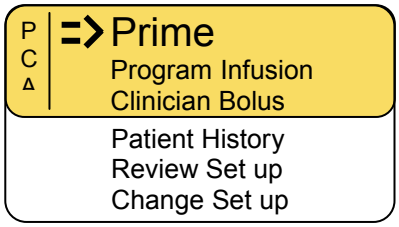
Press START OK. If the pump is unlocked, the PCA Menu will display. If the pump is locked, the PCA Restart Menu will display (See Restart Infusion section if pump is locked)

☞ NOTE: The PCA program automatically locks upon completion of programming.

☞ NOTE: If pump is not already in *PCA* Program refer to Changing Program section for instructions.

☞ NOTE: Whenever you decide to set a new program, follow instructions at the bottom of screen.

3. ***PCA Menu Screen***



The user interface in PCA centers around the PCA menu. From the PCA menu, the user can select:

i. **Prime** – Prime Administration Set
ii. **Program Infusion** – Enter infusion details
iii. **Clinician Bolus** – Infuse extra bolus
iv. **Patient History** – View infusion history of patient
v. **Review Set up** – View pump settings
vi. **Change Set up** – Enables user to change pump settings and switch to other infusion modes.

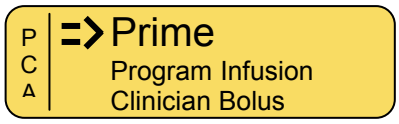
Use ▽ or △ to scroll through options. Select the required option by pressing START OK.

Priming

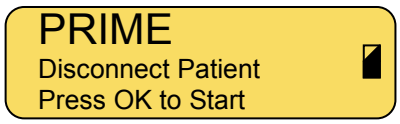
☞ NOTE: Priming is disabled during PCA operation. Always prime the set before starting a program.

Warning: Always disconnect IV tubing from patient before starting priming procedure.

1. Selecting the **Prime** option from the PCA menu, the screen will show the priming screen.



2. Press OK to program priming procedure.



Warning: Ensure the set is not connected to the patient!!

3. Enter the volume to prime the set and press START OK to begin priming procedure. You may stop priming at any time by pressing START OK.

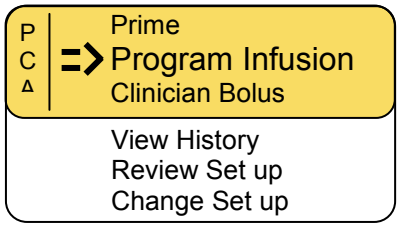
4. The display screen will show a graph indicating the prime operation.

5. Once the priming is completed, the display will change back to the previous screen the pump was in before priming. If more priming is needed, repeat procedure.

Program Infusion

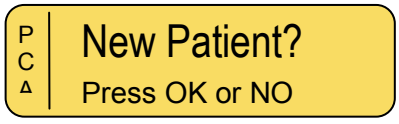
1. ***PCA Menu Screen***

Select **Program Infusion** and press START OK.



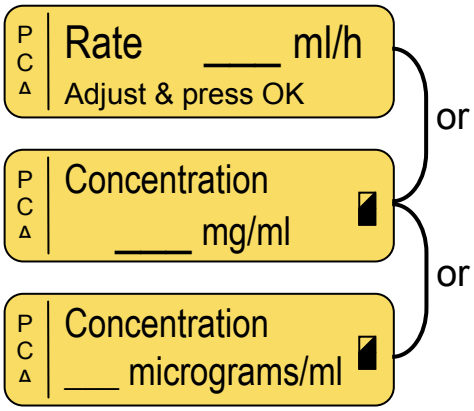
2. ***New Patient Screen***

If programming a protocol for a new patient, select *New Patient* by pressing START OK. If the protocol is not for a new patient, press STOP NO. Pressing STOP NO will clear the volume that has been infused to the current patient.



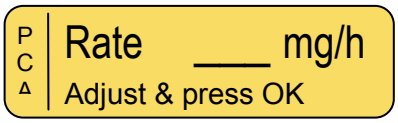
3. ***Rate/Concentration Selection Screen***
   - To program *Rate* in Milliliters per Hour (**ml/hr**), press START OK.
   - To program *Concentration in* Milligrams per Milliliter (**mg/ml**), press STOP NO once.
   - To program *Concentration* in Micrograms per Milliliter (**mµ/ml**), press STOP NO twice.

4. ***Rate or Concentration Screen***
   Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the desired rate or concentration and press START OK.

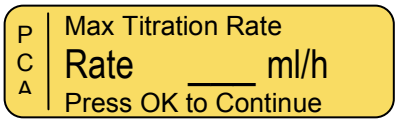


☞ NOTE: To change from *Concentration* back to *Rate*, enter 0 (zero) for Concentration and press START OK.

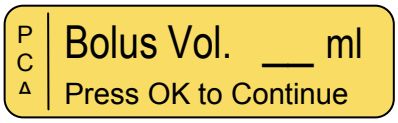
5. ***Concentration Rate Screen***
   (Only When Programming by Concentration)
   Do one of the following:
   - Press START OK to confirm the existing parameters.
   - Enter the desired rate or concentration and press START OK.



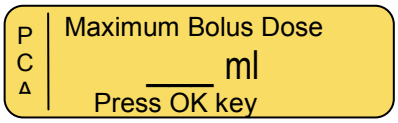
6. ***Rate Titration Limit Screen***
   Enter the maximum rate of titration that can be used in the current protocol and press START OK. Rate can be ml/h, mg/h or mcg/h depending on program selected.



7. ***Bolus Screen***
   Do one of the following (Bolus can be ml, mg, or mcg depending on the program selected):
   - Press START OK to confirm the existing parameters.
   - Enter the desired bolus dose and press START OK.

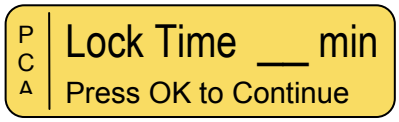


8. ***Bolus Titration Limit Screen***
   Enter the maximum bolus dose that can be used in the current protocol and press START OK. Bolus dose can be ml/h, mg/h or mcg/h depending on program selected.



☞ NOTE: If the “Maximum Bolus Dose” screen does not appear on the pump during programming, go to the “Change Set up” menu to activate “Titration Bolus”

9. ***Lock Time Screen***
The lock time is the amount of time between patient boluses. Do one of the following:

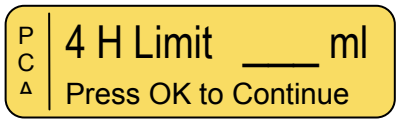


- Press START OK to confirm the existing parameters.
- Enter the desired lock time in minutes and press START OK.

10. ***Hour Limit Screen #1***
As an additional safety precaution, user can program a volume limit over a certain amount of hours. User can set this limit for any amount of time between 1 (One) and 24 (Twenty-Four) hours, or can continue without setting a limit. The default setting is OFF, meaning there is no limit. Do one of the following:

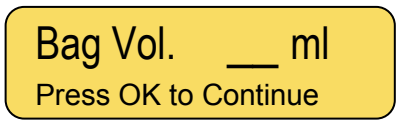
- Press START OK to confirm the existing parameters.
- Enter the desired hours for the limit and press START OK.

11. ***Hour Limit Screen #2***
If an hour limit is entered in previous step, the next step will propt user to enter the maximum amount of volume to be infused over that timeframe. In the screen to the right, 4 (four) was entered in the previous step for the hour limit.
Do one of the following (Limit can be ml, mg, or µg depending on the program selected):



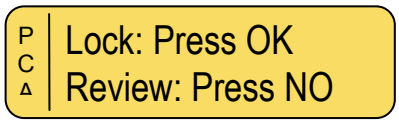
- Press START OK to confirm the existing parameters.
- Enter the desired hours for the limit and press START OK.

12. ***Bag Volume Screen***
Do one of the following:



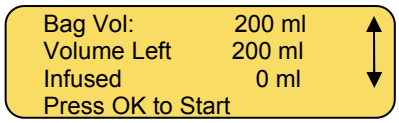
- Press START OK to confirm the existing parameters.
- Enter the desired bolus volume and press START OK.

13. ***Locking Screen***
The pump automatically locks before a PCA infusion program can be completed. Do one of the following:



- Press START OK to lock the PCA program and proceed.
- Press START OK to scroll through the programming again and review or adjust the program.

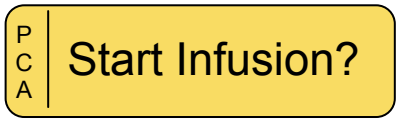
14. ***Accumulation Screen***
The pump displays the accumulation screen with a summary the program entered. User can scroll through the entire program by pressing ▽ or △.



Do one of the following:

- Press START OK to confirm parameters and proceed..
- Press STOP NO to go back and adjust parameters.

15. Press START OK to start infusion.



☞ NOTE: User can confirm that pump is infusing by checking that the drips are displayed on the right side of the screen and that the LED light is blinking green.

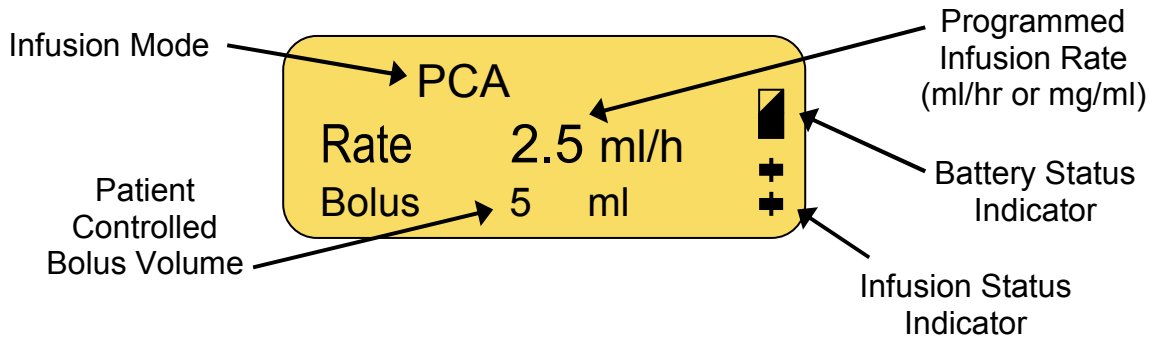
☞ NOTE: To access the PCA menu during operation, press STOP NO once and then hold STOP NO for 3 seconds.

☞ NOTE: LED indicator can be turned off in the main settings menu to save battery power.

☞ NOTE: The BodyGuard is capable of continuous infusion (basal) rates of up to 100 ml/h. However you may use the pump for the delivery of only one drug protocol and the maximum safe ceiling for this regime could be, for example, 30mlh. Users can fix a maximum rate that the pump can be set to in 'Change Set Up' using the Technician Access Code to ensure other users cannot accidentally program the pump to deliver above this safe ceiling. See later section for 'Change Set Up'.

☞ NOTE: The BodyGuard is capable of delivering the bolus dose at up to 1000ml/h. The default setting is 600ml/h designed to deliver any bolus as quickly as possible. Users can adjust this if they want the bolus to be delivered over a longer period in 'Change Set Up' using the Technician Access code.

Interpreting the Display Screen During PCA Infusion



Infusion Mode
The first line of the display indicates that the pump is in the PCA infusion mode.

Infusion Rate
The second line of the display shows the current infusion rate. Depending on whether the user programmed the current protocol in mls or mgs, this will display the rate in either ml/h, mg/h or mcg/h.

Bolus Volume
The third line of the display shows the bolus volume for the current protocol. As with infusion rate, this will be displayed in mls, mgs or mcgs depending on how the current program is set up.

Battery Status
In the right hand margin, you can see the battery and infusion status indicator. The battery symbol will be visible when the pump is not connected to the mains charger. User can check the charge level by monitoring the black fill inside the symbol (i.e. completely black symbol indicates a fully charged battery).

Infusion Status
In the right hand margin, infusion status indicator shows drips moving down the screen when the pump is in operation.

Patient Activated Bolus

A PCA infusion can be programmed to allow the patient to request boluses of a specified volume within predetermined time intervals. The patient can request the bolus by one of the following two methods:

1. ***Using Bolus Cable***
   Press the button on the end of the bolus cable. The bolus cable plugs into the side of the pump where a label reads “Bolus”
2. ***Using Keypad***
   Press the PRIME BOLUS button on the keypad.

☞ NOTE: User can stop bolus at any time by pressing STOP NO.

☞ NOTE: If patient requests more boluses than are allowed, the pump will display “Bolus Locked” and will track the amount of boluses have been requested. The bolus history can be reviewed by scrolling the Info Menu. See “Using History Functions” section of the manual

Clinician Activated Bolus

A Clinician Activated Bolus can be performed *before* starting the PCA infusion or *during* the PCA infusion.

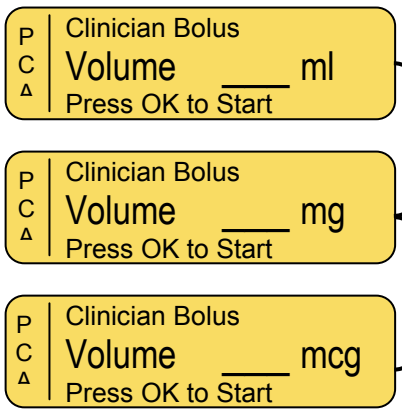
To infuse a Clinician Activated Bolus **before** starting the PCA infusion, perform the following steps:

1. Selecting the **Prime** option from the PCA menu, the screen will show the priming screen. Select Clinician bolus option.

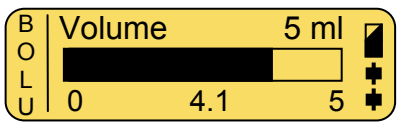
2. Enter Level 2 Technician Code and press START OK.

3. Enter the volume of the Clinician Bolus and press START OK to begin priming procedure. You may stop the bolus at any time by pressing STOP NO.

   The Volume for the Bolus will be in ml, mg or µg depending on the settings of the existing protocol entered for the PCA infusion. To change, go to Program Infusion in the PCA menu and follow the steps until the selection can be made for ml, mg or µg.



4. The display screen will show a graph indicating the Bolus is being infused. The graphical bar displays the amount of the bolus to be infused (clear) and the amount infused (dark).



☞ Once the bolus is completed, the display will change back to the PCA menu.

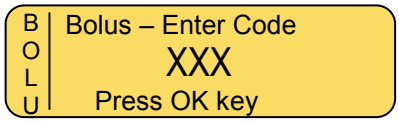
☞ User can stop bolus at any time by pressing STOP NO.

Warning: Boluses will be infused up to the full volume that is requested unless the user stops the bolus manually by pressing STOP NO. This is true even when the volume infused is less than the specified Hour Limit for Volume (e.g. 4 Hr Limit) at the beginning of a bolus and goes over the limit during the bolus.

To infuse a Clinician Activated Bolus **during** a PCA infusion, perform the following steps:

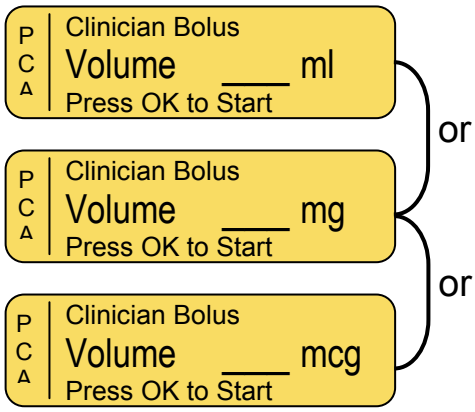
1. During operation, press STOP NO and then press PRIME BOLUS to stop the current infusion and initiate the Clinician Bolus.

2. Enter Level 2 Technician Code and press START OK.

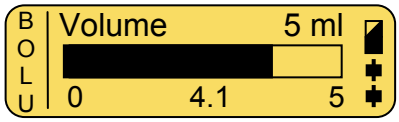


3. Enter the volume of the Clinician Bolus and press START OK to begin priming procedure. You may stop the bolus at any time by pressing STOP NO.

   The Volume for the Bolus will be in ml, mg or µg depending on the settings of the existing protocol entered for the PCA infusion.



4. The display screen will show a graph indicating the Bolus is being infused. The graphical bar displays the amount of the bolus to be infused (clear) and the amount infused (dark).

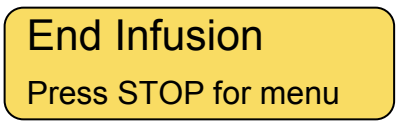


☞ Once the bolus is completed, the pump will resume the original PCA infusion.

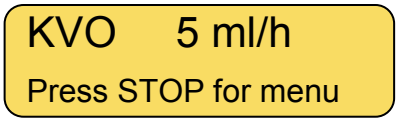
☞ User can stop bolus at any time by pressing STOP NO.

End of Infusion, Restart Infusion, or Bag Change

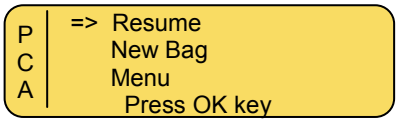
1. ***End Infusion Screen***
   Once the infusion had reached an end (pre-set volume was infused), an alarm sounds and display will show:



2. ***KVO Display***
   The alarm will stop after 4 beeps. The pump will show the pre-set KVO rat. The alarm will sound again every 4 minutes until the user changes the bag or stops the pump.



3. ***PCA Restart Menu***
   This screen displays when:
   (1) The pump is turned OFF and back ON in PCA mode.
   (2) Infusion is stopped by pressing and holding START OK.



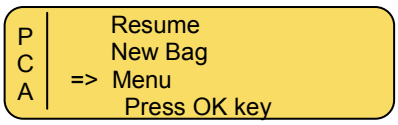
   User can scroll through the following options by pressing ▽ or △.

   - **Restart** – Starts infusion exactly where it left off previously.
   - **New Bag** – Restarts infusion exactly where it left off previously and updates bag volume to be equal to the bag volume originally programmed.
   - **Menu** – Brings user back to the PCA Menu.When asked for a code, enter the Unlock (L2) Code.

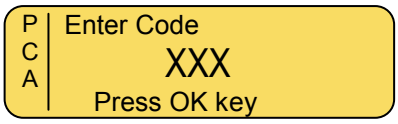
☞ NOTE: If using an infusion set with drip chamber, change to a new infusion bag, but make sure that the drip chamber is half filled and there is no air in the administration set. If using an ambulatory IV, PCA or Epidural set without a drip chamber, priming the line may be needed. Disconnect the set from patient before priming.

Return to PCA Menu

1. ***PCA Restart Menu***
   Scroll to *"Menu"* using ▽ and press START OK.



2. Enter Level 1 Technician Code and press START OK.



Titrating Basal Rate During The Infusion

To change Rate during the infusion, enter the new rate using the keypad and confirm the new rate by entering the **Level 1** Code. The Rate can be increased up to the "**Max Titration Rate**" programmed into the specific infusion.

Titrating Bolus During The Infusion

To change the Bolus during the infusion, press the INFO button seven times until you reach a screen showing the currently programmed Bolus in ml or mg. Use the keypad to enter the new Bolus and confirm the new Bolus by entering the **Level 1** Code. The Bolus can be increased up to the "**Maximum Bolus Dose**" programmed into the specific infusion.

Changing Lock Out Time During The Infusion

1. Stop the infusion by pressing

.
2. Then press and hold

until the screen appears allowing you to access the PCA Menu.
3. Select "Menu" and enter the **Level 2** code.
4. Once in the PCA Menu, select "Program Infusion" and follow the programming instructions to adjust the program. Be sure to tell the pump that there is NOT a New Patient and the Bag Volume should NOT be reset.

Using History Functions

The BodyGuard keeps a rolling 24 hour history of the current patient's infusion delivery. This section addresses how this can be used. There is also a 500 event history log keeping track of the last 500 user actions in a date and time stamped record.

While the pump is delivering medication, pressing the

button repeatedly will scroll through:

- Volume Infused vs. Volume to be Infused
- Battery Level
- Boluses Attempted, Boluses Given & Lock Time Review for the duration of the current delivery
- Program Review Screen - Allows user to check current program parameters without having to stop the infusion
- Date & Time
- Actual Pressure

Press

to stop infusion delivery and then press the

button repeatedly to scroll through:

- Volume and Boluses Given in the Last 24 hours
- Bolus Attempts, Given and Volume Infused Hour-by-Hour for the Last 24 Hours (use the arrow keys to navigate through the hours)
- Chart of Bolus Delivery During the Last 24 Hours, Hour-by-Hour
- Chart of Volume (Including Boluses) Delivered During the Last 24 Hours, Hour-by-Hour

☞ NOTE: Press

to resume infusion when you return to the 'STOP' screen.

Events Log

To access the history of events, you need to access *Change Set Up* using the Level 1 Technician Access Code. The events history carries the last 500 user events (i.e. changes to programs, pump started/ stopped, etc) and the status of the pump (i.e. battery charge, pressure levels, etc). It is not patient specific (i.e. the 500 events are likely to span multiple patients recently treated with that particular pump).

To access the events history:

1. From the main menu scroll to "*Change Set up"* and press

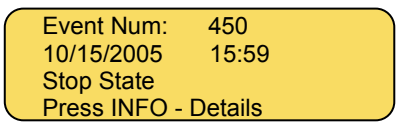
.
2. From the main menu scroll to "*More …"* and press

.
3. Enter the Level 1 Technician Access Code and press

.
4. Scroll down to "*History*" and press

.
5. The screen will now show the most current user event, date, time, etc.

   For example:



☞ NOTE: Each event is assigned a new number and the pump stores the last 500 in memory. After some time, the first event to appear when you enter the events history may be number 754. This means there have been 754 events in this pumps life and events 255-754 are stored in this history. The pump deletes the oldest event in the log each time a new event occurs.

Press and to scroll through events. When you find one of interest, press to display further data relevant to this event on the status of the program and pump at the time of this event. The user can scroll through the information shown here to check what the pump was set up for, whether it was operating on battery or mains, whether it was locked out and what the pressure settings and readings were at that time.

Rate	1ml/h
Volume Left	99.4
Infused	0.1ml
PCA Program	
Battery Operation	
Normal – Level Battery	
Pressure Level Taken	
Pump Unlocked	
Vol. Cal.	540
Pressure Setting	
High	
Pressure DELTA	15
Pressure CAP	255
Pressure Baseline	88
Actual Pressure	88

Setting Pressure Default For Down Occlusion

1. Turn the pump on by pressing and holding the ON OFF until the Self-Test screen appears. If air sensor is OFF, press START OK to confirm.
2. Pump displays program name and status.
   Press START OK . Wait for the Rate screen to display.
3. Press Info twice.
4. Scroll to "Change set up" and press START OK .

   Volume Infused
   Review Set up
   => Change Set up

5. Scroll to "Pressure Default" and press START OK .

   Restart Pump
   => Pressure Default
   Select Program

6. Press ▽ or △ to adjust the level (high, normal, low).

   Pressure setting
   => Normal 14 psi
   Adjust ↓↑ & press OK

7. Press START OK to store the parameter in memory.

☞ NOTE:

- The following pressure parameters can be set:

  Low = 7 psi
  Normal = 14 psi
  High = 21 psi

- The selected pressure level will remain in memory until it is changed.
- The actual pressure can be viewed at any time by scrolling with the info button during operation.
- After a down stream occlusion, infusion will restart from the stop point.

Lock Mode

The *BodyGuard* provides three different level of locking:

- **A** **Keypad Locking:**
  During operation, all keys are disabled excluding the **STOP/NO** and **INFO** key.

- **B** **Program Locking**
  This feature enables the operator to lock out the setting keys, so that entered parameters and set programs cannot be changed once they are set. This option is important, for example, with children as users, when there is a danger that the child might play with the pump and unknowingly change the program; or for home-care patients who repeat the same program every day. Locking the program prevents mistakes in setting.

- **C** **Maximal Rate Locking**
  This feature enables the operator to set a maximal rate for the pump to accept. The program rate then can be adjusted only up to a preset limit.

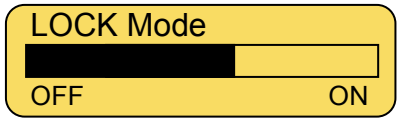
How To Lock

A – Keypad Locking

To Lock Keypad

Press and hold

until the entire graph is black and a beep is heard. The beep indicates that the locking program is turned ON.

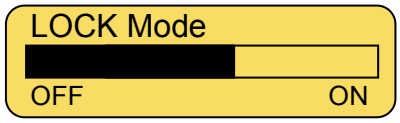


☞ NOTE: The keys are locked in memory until they are unlocked or until entering *Change setup* mode.

To Unlock Keypad

Press and hold

until the entire graph is clear and a beep is heard. The beep indicates that the locking program is turned OFF.



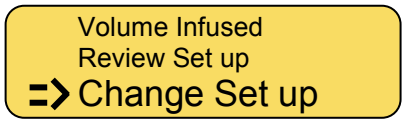
B – Program Locking

1. Press

twice from STOP or setting mode.

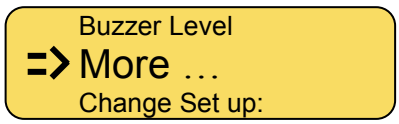
2. Scroll to "Change Set up" option. Press

.



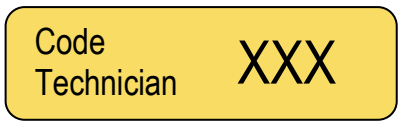
3. Scroll to "More …" and press

.

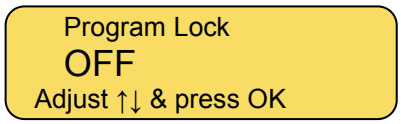


4. Enter *Change Set up* Level 2 code, using the numeric keyboard and press

.



5. Press ▽ or △ to change from OFF to ON and press START OK to approve.



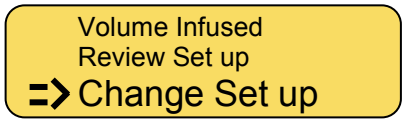
☞ NOTE: The default setting is OFF.

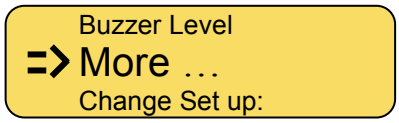
☞ NOTE: Unlock using the same procedure.

C – Maximal Rate locking

1. Press Info twice from STOP or setting mode.
2. Scroll to "Change Set up" option. Press START OK.
3. Scroll to "More …" and press START OK.
4. Enter *Change Set up* Level 1 code, using the numeric keyboard and press START OK.
5. Scroll to "Maximal Rate" option and press START OK.

   Use numeric keys to set desired rate and press START OK.

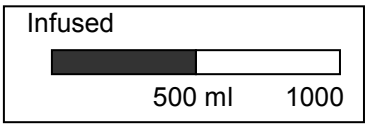
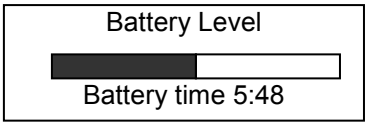
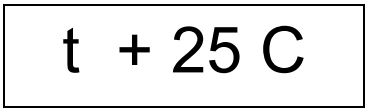
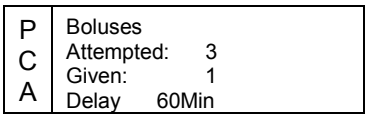
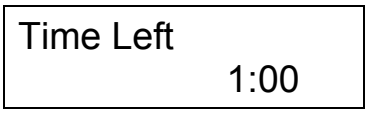
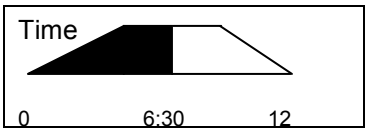
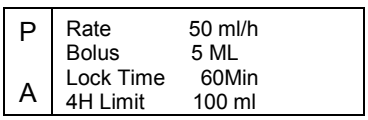
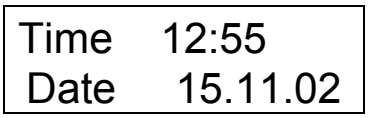
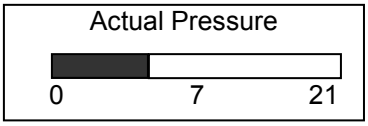




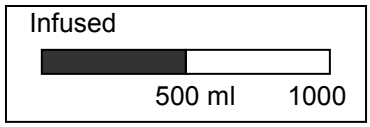
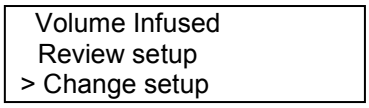
Info Mode

Access the info mode by pressing during operation, data setting or while in the Stop mode.

Pressing during *program operation* will display the following:

Number of Button Presses	Infusion Mode	Information	Screen
One	All programs	Infused Volume Total Volume to Be Infused	
Two	All programs	Battery Status	
Three	Continuous, Intermittent, TPN	Tubing Temperature	
Three	PCA	Boluses History for current program	
Four	Continuous, Intermittent,	Time remaining for the end of the program	
Four	TPN	Program Status in a graphic way	
Four	PCA	Data of current protocol	
Five	All programs	Time and Date	
Six	All programs	Actual Pressure	

Pressing during *data setting* or in the *stop mode*, will display the following:

Number of button presses	Information	Screen
One	Infused Volume Total Volume to Be Infused	 Pressing **STOP/NO** will clear Volume Infused.
Two	Option Selection screen	 To change parameters, select *Change setup*, press **Start/OK** anf follow instructions in the Change setup section. To view current pump settings, select *Review setup*, press **Start/OK** and follow instruction in Review setup section.

☞ NOTE:

- If no selection is made within ten seconds after pressing , the screen will exit the information mode and display the previous screen.
- To exit the information mode after making a selection in *Review Set up*, press once to return to the original screen.
- To exit the information mode after making a selection in *Change Set up*, press .

Review Set up

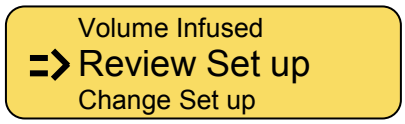
The Review Set up feature is designed to allow you to view the programmable options and other important information about the pump. In Review Set up, settings can be viewed, but not changed.

1. Press

twice.

2. Press to scroll to "Review Set up" option. Press

and the current settings are displayed.



3. To view the setting for a particular option, select the desired option and press

.

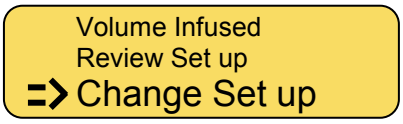
Screen No.	Screen Display	Information
1	Battery Level	Current Battery Level (Empty >>> Full)
2	Program Lock	Option Currently ON or OFF
3	Time, Date	Time and Date
4	Tube Temperature	Tube Temperature
5	Buzzer Level	Current Buzzer Volume Setting
6	Pressure Level	Current Pressure Level Setting
7	Pressure Default	Current Pressure Default Setting
8	Select Program	Current Selected Program
9	Priming Rate	Current Priming Rate Setting
10	Maximal Bolus Volume	Maximal Bolus Volume
11	Bolus Rate	Current Bolus Rate Setting
12	Maximal Rate	Current Maximal Rate Setting
13	KVO Rate	Current KVO Rate Setting
14	Flow Control	Flow Control
15	Air Bubble Size	Current Air Bubble Size Setting
16	Store Last Program	Option Currently ON or OFF
17	Operation LED	Option Currently ON or OFF
18	Time Option	Option Currently ON or OFF
19	Delay Before Start	Option Currently ON or OFF
20	Language	Current Pump Messages Language
21	Serial Number	Pump Serial Number
22	Production Date	Pump Production Date
23	Operation Time	Hours Since Last Service Calibration
24	Software Version	Pump Software Version
25	Volume Calibration	Volumetric Calibration Value
26	Pressure Delta	Pressure Calibration – Delta Value
27	Pressure CAP	Pressure Calibration – Cap Value
28	EXIT	EXIT

Change Set up

The Change setup mode allows you to make changes to the adjustable parameters.

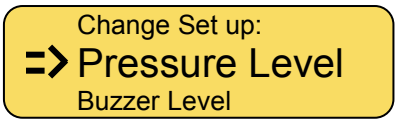
To Access Change Set up:

1. Press twice.
2. Scroll to "Change Set up" option. Press .



To Adjust Pressure Level or Buzzer Level:

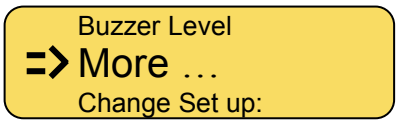
1. Press or to select an option and press .



2. Make adjustment by pressing or and press .

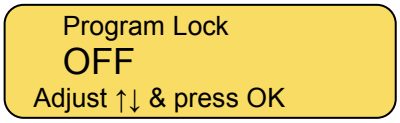
To Adjust Lock Out Option:

1. Scroll to "More …" and press .



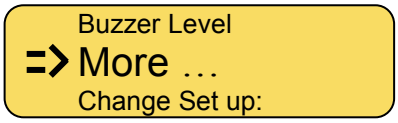
2. Enter **Level 2** Technician Code, using the numeric keyboard and press .

3. Press or to change from OFF to ON and press to approve.



To Adjust Other Parameters:

1. Scroll to "More …" and press .



2. Enter **Level 1** Technician Code, using the numeric keyboard and press .

3. Press or to select an option and press .

4. Adjust the parameter by pressing or , or by using the numeric keypad.

5. Press

to confirm selection and the screen displays “Restart Pump”.

6. Press

to continue.

The table below indicates the adjustable parameters:

Screen No.	Screen Information	Action
1	Pressure Level	Choose pressure level (High 21 psi, Normal 14 psi, Low 7 psi).
2	Buzzer Level	Adjust the buzzer level.
3 Technician code level two	Lock Out	Turn lock out ON/OFF
4 Technician code level one	Restart pump	Restart pump
5	Pressure Default	Select pressure default (High 21 psi, Normal 14 psi, Low 7 psi).
6	Select Program	Select the infusion program
7	Priming Volume	Set the priming volume from 0-60 ml
8	Max. Bolus Volume	Set the Max. bolus volume from 0-100
9	Bolus Rate	Set the bolus rate from 0-1200 ml/hr
10	Maximal Rate	Set the max rate from 0.1-1200 ml/hr
11	KVO rate	Set the KVO rate from 0.1-5.0 ml/hr
12	Flow Control	0-20 drops per ml
13	Air bubble size	Set detectable size from OFF to 1.0 ml
14	Store last program	Turn on to clear all program parameters upon system shut-off. Turn off to save all program parameters upon system shut-off.
15	Operation LED	Turn operation LED ON/OFF
16	Time option	Turn time option ON/OFF. While time option is ON, Continuous, Intermittent and 25 Steps program will be set to Volume over Time.
17	Delay before start	Turn option ON/OFF
18	Language	Enable changing the language of pump messages (only for models in which the software includes more than one language).
19	Time, Date	Set actual time and date
20	History	Indicates injection history

☞ NOTE: While the pump is in programmable mode, all parameters can be set, and parameters used in last program can be confirmed. The memory retention capability is available for the life of the internal battery.

5 – Alarm Conditions and Troubleshooting

Alarm Condition

When the infusion pump detects a problem, four things occur:

- The infusion stops
- An audible alarm is activated
- A message appears on the display screen indicating the cause of the alarm, and
- The LED indicator will change from green to red

☞ NOTE: Pressing

during an alarm mutes the alarm for two minutes.

Troubleshooting

Description	Result	Possible Cause	Required Action
Air in Line Air in Line Press Stop to mute	Infusion stops and an alarm is activated	Air is present in administration Set. The roller or clip on the administration set is closed upstream of the pump. The line was not loaded correctly.	Disconnect line from patient, press STOP/NO. Remove the air, as described on priming section. Open clamp/clip. Re-load the IV line.
Down Occlusion Down Occlusion Press Stop to mute	Infusion stops and an alarm is activated	The roller or clip on the administration set is closed downstream of the pump. Administration set is kinked. Cannula is blocked. Administration set loaded incorrectly. NOTE: Operator may change pressure setting.	Open clamp/clip. Straighten the set. Change the Cannula. Re-load the IV line. Refer to “Setting Down Occlusion” section**.**
Pump Unattended Pump Unattended Press Start key	An alarm is activated	Two minutes has elapsed without a button press during programming.	Press **START/OK** to resume.
Door Open Door Open Close Door	Infusion stops and an alarm is activated	The door of the pump was not closed prior to operation The door has accidentally opened during operation.	Close the door of the pump. Send the pump for service.
Low Battery Low Battery Connect To Charger	Pump will only run for another 30 minutes if it is not connected to mains.	30 Minutes of battery life are remaining.	Place the pump in charger and connect to mains.
End Battery End Battery Connect To Charger	Pump operation stops. The pump cannot be used before being connected to mains.	Battery is depleted.	Place the pump in charger and connect to mains. Wait 2 minutes before operating.

Description	Result	Possible Cause	Required Action
Fatal Error Error xx(number) Send for service	Infusion stops	Fatal internal error has occurred	Restart the pump. If the alarm does not stop pack the pump properly, in its original packaging, and send it for service.
End Program End Program Press stop to mute	Program ends, pump will turn to KVO mode	Current infusion program has been completed.	Press **STOP/NO** to restart a new program or turn the pump OFF.
Missing Key Missing Key Set key & Close Door	Pump will not start	Administration set loaded incorrectly (the key was not located in its place correctly). A set different than the Bodyset/ Microset was loaded in the pump.	Reload the set into the pump as per the instructions. Change the set to a BodySet/ Microset and load it according to instructions.
Lock Out Locked	Setting cannot be changed	Lock Out mode is turned on.	No action required. If changing program is required, unlock the pump and refer to lock section for further instructions.
Lock mode Lock Mode	Setting keys do not function	Lock Out mode is turned on.	No action required. If changing parameters is required, unlock the keys and refer to lock section for further instructions.
Wrong TPN data Wrong TPN data Check Data	Program will not start operating	The set parameters are impossible to perform. Volume or time parameters are incorrect	Check data and change accordingly.

6 – Specifications

Pumping Mechanism:	Piston Pump
Flow Rate:	PCA: 0 to 100 ml/hr in 0.1ml increments All other programs: 0.1 to 100 ml/hr in 0.1ml, 100 to 1200 ml/hr in 1 ml increments.
Priming Rate:	600 ml/hr
Total Infused Volume:	PCA: 0.1 to 1,000 ml. Continuous, TPN, Intermittent: 0.1 to 9999 ml 25 Steps: 0.1 to 9999 ml for each step Accumulated volume for all steps: up to 10 liters
Total Time Setting:	100 hours
Accuracy:	±3%
KVO rate:	0.1 to 5 ml/hr
Air Sensor:	Ultrasonic, adjustable air bubble size
Maximum Pressure:	21 psi Adjustable (High = 21, Normal = 14, Low = 7)
Power Supply:	110-240 VAC, 50/60 Hz. 0.3A max.
Battery:	Rechargeable, Li-Ion 7.2V, 1800mAh (Typical)
Battery Operation at 125 ml/hr:	20 hours (Rechargeable)
Battery Charging:	Automatic when clicked into the Charger that is connected to an AC power source. Six hours needed to charge a fully-depleted battery.
Alarms:	When a problem is detected, the *BodyGuard* displays the following alarms:

- Air in line
- Down Occlusion
- Pump Unattended
- End Program
- Low Battery
- End Battery
- Door Open
- Fatal Error
- Lock Mode
- Lock Out Mode
- Missing Key

☞ NOTE: When this symbol is seen, consult accompanying documents.

BodyGuard Dimensions:	112 x 89 x 32mm. (L x W x H).
Classification	Type CF Equipment (degree of protection against electrical shock)
Housing:	ABS (fire retardant)
Weight	• 280 grams without battery • 390 grams with battery
Electrical Safety	Complies with: **EN 60601-1** (Medical Electrical Equipment Safety), **IEC 60601-2-24** (Infusion pumps and controllers), **IEC 60601-1-4** (Programmable Electrical Medical System)
Standards	Manufactured in accordance to **ISO 9001:2000** and **ISO 13485:2003** **CE marked** (In accordance with the Medical Devices Directive 93/42/EEC)
EMC	The *BodyGuard* Infusion System is designed to be in compliance with EN 60601-1 (safety) and IEC 601-1-2 (EMC).
Environmental Specifications	**Non Operating Conditions** (Transportation and Storage): Temperature: -25°C to 50 °C (-13 °F to + 122 °F) Humidity: 5 % to 100% R.H., non-condensing Air pressure: 48kPa to 110kPa **Operating Conditions:** (The system may not meet all performance specifications if operated outside of the following conditions) Temperature: +18°C to +45 °C (+59 °F to + 113 °F) Humidity: 20 % to 90% R.H. at +40 °C, non-condensing Air pressure: 70kPa to 110kPa
IV Administration set	Dedicated IV administration sets with anti-siphon valve.

7 – Service and Maintenance

Cleaning

Before connecting the pump to a patient, and periodically during use, clean the unit using a lint-free cloth lightly dampened with warm water and a mild detergent or disinfectant.

Warning: Always turn the pump off and remove the battery before cleaning.

Warning: Always unplug the charger from AC power before cleaning.

Caution: Do not clean the pump or charger with chemicals such as Xylene, Acetone or similar solvents. These chemicals can cause damage to plastic components and paint. Use a lint-free cloth dampened with warm water and a mild detergent or disinfectant.

Caution: Do not soak or immerse any part of the pump or charger in water.

Storage

If the pump is to be stored for an extended period, it should be cleaned and the battery fully charged. Store in a clean, dry atmosphere at room temperature and, if available, employ the original packaging for protection.

Perform functional tests and ensure that battery is fully charged once every three months.

Battery Operation

The *BodyGuard* pump can operate on battery power which enables operation when the patient is being moved or during electrical power failure. When the pump operates on battery power, the AC icon is off. At full charge, the standard battery provides 15-17 hours of operation at an infusion rate of 125 ml/hr.

⚠ **Warning:** Do not operate the pump on AC power if the battery is not loaded in the pump for back up.

☞ **Note:** When the pump is not in use, click the pump into the Charger and plug the system into an AC wall outlet (if possible) to charge battery.

☞ **Note:** After the “End Battery“ signal has been activated or following long periods of storage, wait 2 minutes after the pump has been connected to an AC power supply before operating.

⚠ **Caution:** Leaving the battery in an uncharged state for a long period of time may damage the battery.

☞ **Note:** Whenever possible, use the pump connected to an AC power supply via the charging unit. This preserves the battery power supply for emergency use or for situations where the AC power is not available.

☞ **Note:** Replace the battery **once** every two years.

LIMITED WARRANTY

The *BodyGuard* Infusion Pump has been carefully manufactured from the highest quality components.

Caesarea Medical Electronics Ltd. (CME) guarantees the pump against defects in material and workmanship for twelve (12) months from date of purchase by the original purchaser.

CME's obligation, or that of its designated representative under this Limited Warranty, shall be limited, at CME's option, or that of its designated representative, to repairing or replacing pumps, which upon examination, are found to be defective in material or workmanship. The repair or replacement of any product under this Limited Warranty shall not extend the above-mentioned Warranty period.

All repairs under this Limited Warranty should be undertaken only by qualified, trained service personnel. In the event that a pump is found to be defective during the warranty period, the purchaser shall notify CME or its designated representative within thirty (30) days after such defect is discovered.

The defective pump should be sent immediately to CME or its designated representative for inspection, repair or replacement. Shipping costs are the purchaser's responsibility.

Material returned to CME or its designated representative should be properly packaged using CME shipping cartons and inserts. Inadequate packaging may result in severe pump damage.

This Limited Warranty shall not apply to defects or damage caused, wholly or in part, by negligence, spilt fluids, dropping of the pump, misuse, abuse, improper installation or alteration by anyone other than qualified, trained personnel; or to damage resulting from inadequate packaging in shipping the pump to CME or its designated representative.

If, after inspection, CME or its designated representative is unable to identify a problem, CME or its designated representative reserves the right to invoice purchaser for such inspection.

This Limited Warranty is the sole and entire warranty pertaining to CME's products and is in lieu of and excludes all other warranties of any nature whatsoever, whether stated, or implied or arising by operation of law, trade, usage or course of dealing, including but not limited to, warranties of merchantability and warranties of fitness for a particular purpose. Purchaser expressly agrees that the remedies granted to it under this limited warranty are purchaser's sole and exclusive remedies with respect to any claim of purchaser arising under this Limited Warranty.

Managing Director

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